The predictive relationship between physical activity and functional recovery in an acute low back pain population.

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PhD

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Abstract

Advice to remain active and normalisation of activity are commonly prescribed in the management of low back pain (LBP). However, no research has assessed whether objective measurements of physical activity predict outcome and recovery in acute low back pain. The aims of this study were to assess the predictive relationship between activity and disability at 3 months in an acute LBP population. This prospective cohort study recruited 101 consenting patients with acute LBP (< 6 weeks) who completed the Roland Morris Disability Questionnaire (RMDQ), the Visual Analogue Scale (VAS), and resumption of full 'normal' activity question (Y/N), at baseline, 3 months and 1 year. Physical activity was measured for 7 days at both baseline and at 3 months with an RT3 accelerometer recall questionnaire and at 1 year with an activity recall questionnaire. Objective and non-objective measures of physical activity at baseline and change in activity from baseline to 3 months were not independent predictors of RMDQ ($p > 0.05$) or RMDQ change ($p > 0.05$) over 3 months or 1 year ($p > 0.05$). A self-report of a return to full 'normal' activities was significantly associated with greater RMDQ change at 3 months ($p < 0.001$). Paired t tests found no significant change in activity levels measured with the RT3 ($p = 0.57$) or the recall questionnaire ($p = 0.38$) from baseline to 3 months. At 1 year the only predictor of a lower RMDQ was a lower Fear Avoidance Belief Questionnaire- work component (FABQW) score at baseline. A number of measures of activity in univariate analyses predicted a report of LBP chronicity at 1 year including: a lower Baecke Sports Index score at 1 year, a lower change in activity from baseline to 1 year (BPAQ change), and a higher work activity score at baseline ($p < 0.05$). The report of not returning to full normal activities at 3 months explained 9.0% of the variance in chronic LBP at 1 year. However, none of the measures of activity either prior to the LBP episode, at baseline, 3 months, or at 1 year predicted RMDQ score at 1 year or a report of LBP chronicity in multiple regression analyses ($p > 0.05$). These results question the predictive role of physical activity in LBP recovery, and the assumption that activity levels change as LBP symptoms resolve. The importance of a patient's perception of activity limitation in recovery from acute LBP was also highlighted.

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List of Abbreviations

7 D-PAR	Seven Day Recall Questionnaires
ADMR	Average Daily Metabolic Rate
BDI	Beck Depression Inventory
BPAQ	Baecke Physical Activity Questionnaire
CHAMPS	42 item Community Healthy Activities Model Program for Seniors
COPD	Chronic Obstructive Pulmonary Disease
CV	Coefficient of Variation
DLW	Doubly Labelled Water
EE	Energy Expenditure
FABQ	Fear-Avoidance Beliefs Questionnaire
FABQPA	Fear-Avoidance Beliefs Questionnaire Physical Activity
FABQW	Fear-Avoidance Beliefs Questionnaire Work
FQPA	Freiburger Questionnaire on Physical Activity
GHQ12	General Health Questionnaire
GPS	Global Positioning System
HSE	Health Survey for England
IC	Indirect Calorimerty
IPAQ	International Physical Activity Questionnaire
LBP	Low Back Pain
MCID	Minimally Clinically Important Difference
METS	Metabolic Equivalents Tasks
NRS	Numerical Rating Scale
NSLBP	Non-Specific Low Back Pain
ODI	Oswestry Disability Questionnaire
PA	Physical Activity
PAEE	Physical Activity Energy Expenditure
PAD	Physical Activity Decline
PAL	Physical Activity Level
PAL-0	Baseline Activity Level
PAL-1	Physical Activity Level at 1 year
PCS	Pain Catastrophising Scale
PE	Physical Exercise
PHODA	Photograph Series of Daily Activities

PPV	Positive Predictive Value
PT	Physiotherapist
PVAQ	Pain vigilance and awareness
PWR	Past Week Recall
QBPDS	Quebec Back Pain Disability Scale
RCT	Randomized Controlled Trial
RPM	Revolutions per minute
RMDQ	24-item Roland Morris Disability Questionnaire
RMR	Resting Metabolic Rate
SAI	Sport Activity Index
SBI	Pain Symptoms Bothersomeness Index
SCL-90	Symptom Checklist-90
SEM	Standard Error of the Mean
SFI	Pain Symptoms Frequency
SQUASH	Short Questionnaire to Assess Health Enhancing Physical Activity
TSK	Tampa Scale for Kinesiophobia
VAS	Visual Analogue Scale
VM	Vector Magnitude

Preface

This research represents a journey to better understand how activity might relate to a person's recovery from back pain. It is clear that through such research we gain knowledge and greater understanding however, there is still much that will not be answered through such lines of enquiry.

Imagination is more important than knowledge. For knowledge is limited to all we now know and understand, while imagination embraces the entire world, and all there ever will be to know and understand."

Albert Einstein

CONFERENCE PRESENTATIONS AND PUBLICATIONS

Meredith Perry, Paul Hendrick, Leigh Hale, David Baxter, Stephan Milosavljevic, Sarah Dean, Suzanne McDonough, Deirdre Hurley. (2010) Utility of the RT3 activity monitor in free living. Applied Ergonomics 41, 469-476

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Hendrick, P, Perry M, Hale L, Bell M, Hurley-Osing D, McDonough S, Milosavljevic S, Baxter D (2008) The role of physical activity in functional recovery in a low back pain: a longitudinal analysis. Rehabilitation and Disability Research Theme, University of Otago, Dunedin NZ.

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PA Hendrick, LA Hale, ML Bell, S Milosavljevic, DA Hurley-Osing, SM McDonough and DG Baxter. The relationship between objective activity change and patient's perceptions of activity change and low back pain recovery (2010). The Australian Pain Society and the New Zealand Pain Society Combined Annual Scientific Meeting, Gold Coast, Australia

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CHAPTER I

Introduction

1 Introduction

This thesis outlines a body of work to research and investigate how activity relates to recovery from an acute episode of back pain. This research has been prompted by recognition that cost-effective strategies for preventing the consequences of low back pain (LBP) in both the short and long-term are required (Majid and Truumees 2008). However, despite the growth in research and focus on LBP in primary care, it remains a major health problem among populations in western industrialised countries; in particular it is a substantial burden in terms of expenses, absenteeism, and disability in the community (Maniadakis and Gray 2000; Dagenais, Caro et al. 2008). Effective strategies to manage LBP and prevent recurrence and chronicity remain elusive (Kent and Keating 2005; van der Roer, Goossens et al. 2005; Refshauge and Maher 2006). As such, guidelines have been developed to synthesise the evidence base to guide clinicians to more effectively manage both acute and chronic LBP (Bekkering, Hendriks et al. 2003). A critical review of the guidelines shows that activity advice and prescription is a consistent feature in the management of LBP (Arnau, Vallano et al. 2006). However, little is known on the role of activity in acute LBP populations, and whether patient's activity levels relate to outcomes in either the short or long-term.

Activity is thought to play a key role in the incidence, reoccurrence, and outcome in LBP (Burton, Waddell et al. 1999; Hurwitz, Morgenstern et al. 2005; Enthoven, Skargren et al. 2006; Heneweer, Vanhees et al. 2009). However, these findings have been disputed and several studies have reported no relationship between activity and incidence of LBP (Verbunt, Sieben et al. 2005), and outcomes in either the short or long term (Mortimer, Pernold et al. 2006; Bousema, Verbunt et al. 2007). Models of deconditioning in LBP have been proposed (Verbunt, Seelen et al. 2003) and disputed (Smeets and Wittink 2007), and thus the role of activity in LBP remains inconclusive, particularly as to whether a patient's activity levels predict outcome in the long-term.

The current study outlines a body of research that investigated the predictive relationships between activity levels and outcome measures of disability and pain, both short and long-term, in patients with acute LBP. The following description is an outline of the research and summary of main findings and conclusions from the PhD research (Figure 1-1)

In Chapter II a literature review outlines the rationale for measurement of activity levels in free living; issues associated with the measurement of activity in free living including activity behaviour; and the relationships between activity and other chronic health conditions. A summary of the activity measurement tools employed in free living activity measurement is discussed, focusing on issues of validity, reliability, and utility. A rationale for the use of the RT3 activity monitor as the primary objective measure of activity in field research is presented in both normal populations and those with health-related issues. A brief overview of self-report measures of activity employed in free-living research is also presented, and the relative strengths and weaknesses of objective versus non-objective measures of activity are further discussed.

The role of activity in LBP is debated in Chapter III, including evidence for current clinical guidelines on activity advice. A current research update is presented on the relationships between activity and the aetiology and management of LBP, and our current understanding of the role of physical activity (PA) in the prognosis of primary care LBP. Also, the factors associated with LBP recovery in both the short-term and long-term are briefly summarized, including the deconditioning model and the theoretical role that activity plays in prognosis within various LBP populations. Research studies which have measured activity in LBP populations with objective activity measures are presented and discussed to show the types of activity measurement and protocol employed, the aims of the research, and consequently our current understanding of the role that objectively measured activity has in LBP research.

A discussion of outcomes employed in longitudinal LBP research, and a summary and justification of the Roland Morris Disability Questionnaire (RMDQ) as the primary outcome measure is presented. Confounding factors in the measurement of free living activity and health-related outcomes in LBP populations are summarized. Evidence for the main factors considered as potential confounders/mediators in the relationship between activity and LBP are discussed, and the validity of the measurement tools briefly summarized. The evidence for the role of activity in LBP has not been previously investigated and thus a systematic review in this area is required.

A systematic review of the evidence for the role of activity in LBP is evaluated in Chapter IV. This study included research in which activity was statistically evaluated against LBP outcome measures, and included both cross-sectional and longitudinal designs. This systematic review sought cohort and cross-sectional studies using: OVID, CINAHL, Medline,

AMED, Embase, Biomed, PubMed-National Library of Medicine, Proquest, and Cochrane Databases, and hand-searches of reference lists. Twelve studies (seven cohort and five cross-sectional) were included. One prospective study reported a statistically significant relationship between leisure time activity and LBP outcomes, and one cross-sectional study found lower levels of sporting activity were associated with higher levels of pain and disability. All other studies (n = 10) found no relationship between the measures of activity levels and either pain or disability. However, heterogeneity of study designs, particularly in terms of activity measurement, made comparisons between studies difficult. These data suggested that the activity levels of patients with non-specific LBP are not associated with, nor predictive of, disability or pain levels. Evidence for the main factors considered as potential confounders/mediators in the relationship between activity and LBP employed in studies measuring activity are further discussed. Further discussion in terms of future study design, and in particular prospective adequately powered research employing validated activity measurement, is recommended to better evaluate the relationships between PA and LBP in free living. The results of this study have been published recently (Hendrick, Milosavljevic et al. 2010).

Chapter V details a pilot study carried out to field test the RT3 triaxial accelerometer in a repeated measures design involving normal healthy subjects. The aims of this pilot study were to assess the sources of activity variance measured with an RT3 over repeated measurements within healthy subjects, and to investigate the utility of the RT3 as a measurement device for free-living research. The results allowed calculation of the potential sources of activity variance of the RT3 in free living, and the number of days of activity measurement required to reliably estimate activity levels within this population. The utility results provided an estimation of the reasons for and causes of data loss employing the RT3 in the field. These results allowed the development of a larger prospective adequately powered study to assess activity change within a LBP population and to investigate the relationship between activity change and measures of LBP disability over time. The results of this pilot study have been recently published (Perry, Hendrick et al. 2010)

The aims, hypothesis, and methodology of the main study are described in Chapter VI. This chapter outlines a study to investigate the relationships between free living activity and measures of pain and disability at 3 and 12 months in an acute LBP population. This includes a description of sample collection, sample size estimation, inclusion criteria, measurement process, data collection protocol and statistical analyses used to investigate the relationship

between activity change, as measured with both objective (RT3) and non-objective measures (activity questionnaires), and LBP outcomes in the short (3 months) and longer term (12 months). The methodology for this research has been previously published (Hendrick, Milosavljevic et al. 2009).

The results of the study are presented in Chapter VII. In brief, this prospective cohort study recruited 101 consenting patients with acute LBP. Measurement of activity was carried out at baseline, 3 months and at 1 year. The results of the research are presented in two separate sections:

1. The results of the predictive relationship between activity at baseline to 3 months (as measured with the RT3 and activity questionnaire) and measures of LBP disability and pain.
2. The results of the predictive relationship between activity at baseline, 3 months and at 1 year as measured with the RT3 and activity questionnaires and measures of disability and LBP chronicity.

The results found that measures of PA at baseline and change in activity from baseline to 3 months were not independent predictors of LBP disability at 3 months. There was also no significant change in activity levels measured with either the RT3 or the recall questionnaire from baseline to 3 months. At 1 year higher levels of work activity and a lower level of sport activity post LBP were independent predictors of unresolved LBP. However, none of these activity variables measured pre-episode of LBP, at baseline, or 3 months were significant predictors of LBP disability at 3 months or 1 year in the multiple regression models. A discussion of the findings from this component of the 3 month results and 1 year results are presented in relation to current literature.

An overall discussion of the systematic review and activity study in relation to the current understanding of the role of activity in LBP prognosis is presented in Chapter VIII. The evidence from this research does not support PA playing a role in low back pain recovery or in reducing levels of pain and disability. However, a number of areas identified from the current work warrant further study including investigation of activity employing a variety of activity measurement tools to better understand the complex interactions of activity and disability. Also, the influences of potential confounders to the relationship between activity and LBP outcome including behavioural and psychosocial influences warrants further study.

Issues of relative internal and external validity of the research design are debated, including potential limitations and generalisability of the research findings, and potential directions for future research considered.

Conclusions and clinical implications from this body of research are discussed in Chapter IX. In summary, this research did not find evidence for a predictive dose response relationship between activity and either pain or disability; however, the research outlined the difficulties of measuring and monitoring free living activity and particularly when attempting to investigate potential interactions with LBP outcomes. Interactions between activity and LBP are complex and multi-modal and with the known health benefits the results support current recommendations for patients to maintain and restore their normal activity as part of the overall management of LBP. However, these findings highlight the importance of patient perceptions of normality of activity rather than achievement of a certain level or type of activity for recovery from an acute episode of LBP. An overview of the research in relation to clinical practice, current LBP guidelines and future research directions is discussed.

Also, a number of published student projects and collaborative work in the field of activity measurement and the role of activity in LBP are also acknowledged which laid a foundation for the research in the main study. This research has also helped to validate the research design and provided valuable information on the measurement of activity with the RT3 activity monitor (Hendrick, Bell et al. 2009; Hendrick, Boyd et al. 2010) and to further explore the relationships between activity and LBP outcomes (Hendrick, Te Wake et al. 2010).

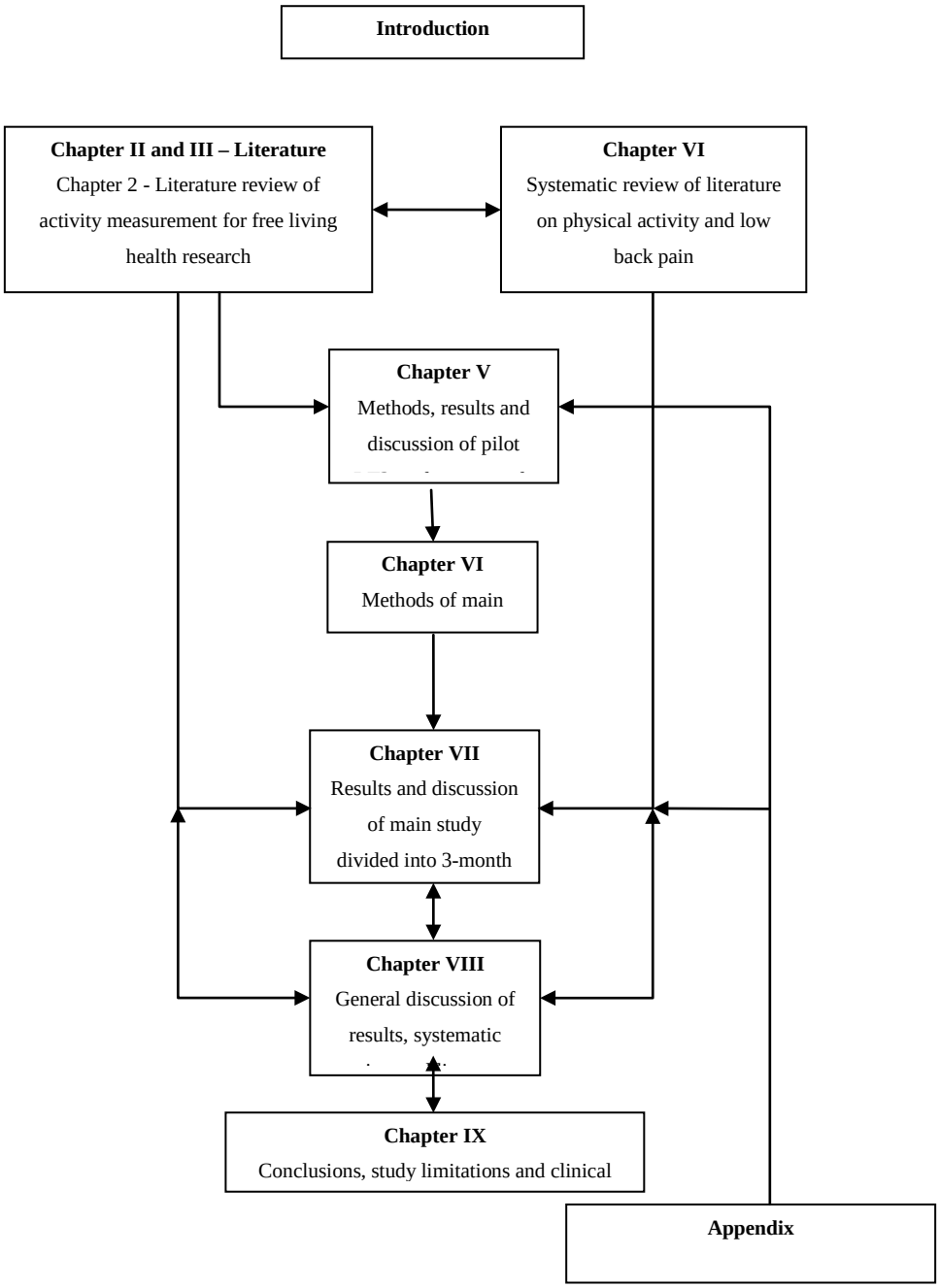

Figure 1-1. Layout and organisation of thesis

CHAPTER II

Literature Review of Physical Activity Measurement

2 Physical activity measurement: A narrative review

The current chapter reviews the literature relating to the rationale and measurement of activity in free living, and briefly summarises issues related to validity and reliability of various measures of activity in free living. In particular the review focuses on the RT3 triaxial accelerometer and the evidence for the use of this device in free living activity measurement. The review discusses the relative strengths and weaknesses of objective and non-objective measures of activity measurement in free living studies. The review summarises our main understanding in this field in relation to activity measurement for health related research and identifies gaps in knowledge and directions for further research and study.

2.1 Measurement of physical activity in free living

There is an increasing focus on the role of PA in public health (Haskell 1994; Oberg 2007). Research has sought to better quantify activity, in order to develop dose response relationships between levels and types of activity, and change in activity in chronic health conditions (Oja 2001; Warburton, Nicol et al. 2006). Free living activity measurement is defined as a measure of activity undertaken in day to day life including occupational, transport, household and leisure activities (Bouchard and Trudeau 2008), and it is recognised that measurement of these various domains of activity is central to the validity of research into PA and it's role in health (Janz 2006). Physical activity can also be described as having four dimensions: duration (minutes/hours) , frequency (time per week/per month), intensity (rate of energy expenditure), and circumstances or purpose of the activity (Ken-Dror, Lerman et al. 2005), and therefore it is important that the measurement construct captures and measures each of these dimensions in free living.

There are also a number of recognised potential confounders to the measurement of PA in free living; these include gender, age, race/ethnicity, marital status, education, employment, and household income (Ransdell and Wells 1998; Sparling and Snow 2002; Steffen, Arnett et al. 2006). Activity has been shown to vary depending on each of these factors (Harreby, Hesselsoe et al. 1997) and the effects of these potential interactions to vary within population groups (Seefeldt, Malina et al. 2002). Therefore the effects of these potential confounders need to be assessed for their relative importance for each particular group (Wareham and

Rennie 1998). Further discussion and evaluation of potential confounders to be considered in prospective research investigating the relationship between activity and LBP outcomes are discussed in Chapter IV Section 4.3.3.

Physical activity questionnaires, although a non-objective measure of activity, remain the only practical means of assessing activity levels cheaply and effectively in population-based studies (Booth 2000). A large number of activity-based questionnaires have been developed which focus on different populations (Crocker, Bailey et al. 1997; Harada, Chiu et al. 2001), occupations (Reis, DuBose et al. 2005), encompassing various dimensions of activities of daily living (Jacobs Jr, Ainsworth et al. 1993), and requiring activity recall over different time periods (Friedenreich, Courneya et al. 2006; Besson, Brage et al. 2010); however the most common period of activity recall measurement is 7 days (Matton, Wijndaele et al. 2007; Sloane, Snyder et al. 2009). For the purposes of this research a validated seven day recall questionnaire was chosen to evaluate PA for 7 days in free living, and a validated questionnaire to measure habitual activity in free living was also chosen to investigate "normal" levels of activity over a longer period of time. The following section describes the evidence for the Seven Day Recall Questionnaire (7D-PAR) and the Baecke Physical Activity Questionnaire (BPAQ) to measure free living activity. The 7D-PAR was chosen to allow a validated prospective measurement and recording of activity over a 7-day period at two separate time points within this LBP population whilst the BPAQ was employed to provide a measure of routine activity pre-LBP and also as a comparative measure at the 1-year time point.

2.2 The Seven Day Recall Questionnaire

The 7D-PAR is an administered recall questionnaire via structured interview. Subjects are asked to recall the amount of time spent in sleep, moderate, hard, and very hard physical activities exceeding 10 minutes in duration during the last seven day period. The average amount of time spent in light, moderate, hard, and very hard activities allows the calculation of the daily energy expenditure of the participant over the seven days. The 7D-PAR is accepted as providing reasonable validity as a measure of free living energy expenditure (EE) within various populations (Johansen, Painter et al. 2001; Washburn, Jacobsen et al. 2003), and has been employed as a comparative measure of criterion validity in trials investigating reliability and validity of triaxial accelerometry in free living (Matthews and Freedson 1995; Hayden-Wade, Coleman et al. 2003; Dubbert, Vander Weg et al. 2004).

The questionnaire has undergone extensive study as a measure of free living EE as compared to doubly labelled water (DLW) (Philippaerts, Westerterp et al. 1999; Sallis and Saelens 2000; Leenders, Sherman et al. 2001). These results show some degree of variability in the relationships between recalled activity and measured EE: the 7D-PAR has been found to both under and over estimate EE in free living. The 7D-PAR overestimated EE compared to DLW by 4132 ± 1356 kJ·d-1 (30.6 ± 9.9%) in a group of young males (Irwin, Ainsworth et al. 2001). The 7D-PAR alternatively overestimated total EE in a small sample of healthy older men by 10.8% (Bonnefoy, Normand et al. 2001), and by 3.4% in a small group of obese middle-age women (Racette, Schoeller et al. 1995). However, Washburn et al. 2003 found no significant group difference in total EE in a group of young healthy males, and reported that peak oxygen uptake, gender, and percentage fat accounted for 86% of the reporting error in total EE when compared to using the 7D-PAR. These results confirm that that there are numerous potential errors in converting self-reported PA into measures of EE (Neilson, Robson et al. 2008). Potential discrepancies between recall questionnaires and DLW estimates may be partly attributable to non-inclusion of key activities; questionnaires and DLW measuring different time periods; and the inaccurate assignment of metabolic equivalents (METS) to self-reported activities (Neilson, Robson et al. 2008). These findings are also supported by a recent review which found that estimates of self-report measures of PA were both higher and lower than directly measured levels of PA (Prince, Adamo et al. 2008). Although there are noted limitations to the use of recall questionnaires to accurately estimate free living EE, the 7D-PAR was found to be only one of a few questionnaires to demonstrate a reasonable degree of reliability and ability to rank healthy older men according to PA (Bonnefoy, Normand et al. 2001). The instrument also demonstrates moderate to high interviewer reliability (ICC = 0.85) (Washburn, Jacobsen et al. 2003) when employing trained individuals to carry out the interviews.

Construct validity of the 7D-PAR has also been investigated by correlating the measures of EE to measures of activity from accelerometry. Correlations between the 7D-PAR and measures of PA from activity monitors vary considerably: from (r = 89 - 0.99) between 7-DAR and the RT3 (Peterson, Yates et al. 2005), to (r = 0.542 – 0.416) between the 7D-PAR and the Tritrac triaxial accelerometer (Lemmer, Ivey et al. 2001) in a mixed group of young and elderly participants undergoing a strength training programme. Longitudinal correlations between the 7D-PAR and the RT3 show moderate agreement with correlation coefficients of 0.54 (baseline), 0.24 (year 1), and 0.53 (year 2) within an elderly population post-cancer

surgery (Sloane, Snyder et al. 2009). Overall the RT3 tended to overestimate (compared to the 7D-PAR) hours of moderate and hard activity within this population. Another study comparing the RT3 and the 7D-PAR in a small group of patients with mental illness reported high test-retest reliability (IC = 0.97) and a moderate correlation coefficient for total EE (r = 0.43), but low correlations for moderate (r = 0.16) and vigorous (r = 0.08) activities (Soundy, Taylor et al. 2007). These results show that variations between questionnaires and recall questionnaires are dependent upon the sampled population and the time period of measurement, as well as the measures and units of activity and EE utilised from the accelerometer employed in each of the studies.

2.3 The Baecke Physical Activity Questionnaire

The BPAQ provides information on habitual activity levels over the previous year (Baecke, Burema et al. 1982), and is divided into three sections (work, sports and leisure) which are individually scored (Baecke, Burema et al. 1982) to provide a measure of habitual activity within each of these domains. The BPAQ demonstrates good repeatability and relative validity in free living populations (Pols, Peeters et al. 1995), high test-re-test reliability (ICC = 0.89) in populations with LBP (Jacob, Baras et al. 2001), and has been previously employed as a measure of habitual activity within populations with LBP (Smeets, Maher et al. 2009). The BPAQ demonstrates reasonable validity and reliability in other patient populations (Ono, Hirata et al. 2007) and normal populations (Florindo and do Rosario Dias de Oliveira Latorre 2003), and has thus been utilized as a measure of habitual activity within both “normal” and disabled groups.

2.4 Limitations of questionnaires to measure activity in free living

It is recognised that recall questionnaires have a number of limitations to the measurement of free living PA. Although questionnaires offer a measurement tool which can measure PA within large sample sizes at relatively low cost (Jacobs Jr, Ainsworth et al.; Bassett 2003; Orsini, Bellocco et al. 2008), research has shown considerable measurement error and recall bias using questionnaires (Janz 2006; Neilson, Robson et al. 2008), particularly due to the nature of retrospective activity reporting which can be prone to biases and inaccuracies (Hertogh, Monninkhof et al. 2008). A recent review found only low to moderate correlation between activity recall questionnaires and activity monitors (Prince, Adamo et al. 2008): self-report measures of PA were found to be potentially both higher and lower than objective

measures, making corrections in analysis and interpretation of inter-relationships problematic. Therefore the noted limitations in recall based questionnaires have led to the increasing use of objective measurements of activity in the field including pedometers (Lubans, Morgan et al. 2009), heart rate monitors (Hussey and Wilson 2003), global positioning system (GPS) (Ermes, Parkka et al. 2008), and accelerometer-based activity monitors (Westerterp 1999; Ermes, Parkka et al. 2008) as objective measures of activity. As research has shown that relationships between health outcomes and PA are dependent upon the measure of activity (Rowlands, Ingledew et al. 2000), there has been an increasing emphasis on the need to establish effective and valid methods to assess activity in free living. The following section discusses the use of activity monitors to measure activity and in particular reviews the literature on the evidence for the RT3 as a measure of free living activity.

2.5 Objective measures of activity

Activity monitors offer a means of measuring the various dimensions of free living activity over time and to look at specific activity behaviours and changes in activity (Bussmann, Ebner-Priemer et al. 2009). Accelerometers are mechanical devices, usually worn on the waist, providing a direct and objective measure of the intensity, duration, and frequency of movement associated with PA in free living (Schutz, Weinsier et al. 2001). They are able to estimate PA by generating acceleration counts from a piezoelectric mass that undergoes deformation when exposed to acceleration (body movement) and thereby produce a voltage signal (Powell, Jones et al. 2003; Moeller, Korsholm et al. 2008). This analogue signal is converted to a digital series of numbers which are the “raw” counts. The raw count is then computed to PA counts by integrated algorithms or zero-crossing method (Chen and Bassett Jr 2005). The devices can be affixed to the individual to wear in free living, and in-built memory systems allow continual monitoring over relatively long periods (Godfrey, Conway et al. 2008). Ambulatory devices have thus made it possible to classify movement and measure long-term trends in activity.

However limitations with such devices remain: waist worn activity monitors show a poor ability to detect arm movements or external work such as walking on an incline (Bassett, Ainsworth et al. 2000). Also, acceleration is used to construct a measure of activity or EE via specific proprietary algorithms which convert acceleration data into steps (Grant, Ryan et al. 2006), vector magnitude (VM) counts, and activity EE (Hussey, Bennett et al. 2009). As each accelerometer employs different proprietary equations and algorithms to produce measures of

PA and EE related to activity, this limits the external validity and applicability of results of one study to another study. It is also recognised that calibration equations need to be developed, validated, and tested in specific patient populations under investigation (Lamonte and Ainsworth 2001). This is particularly important where it is known that the relationships between EE and PA are multifactorial in nature (Irwin, Ainsworth et al. 2001). Various methods have been suggested to utilise and analyse accelerometry data to estimate free living activity (Wickel and Welk 2010), and to establish thresholds for free living activity to differentiate between levels of activity (Mathie, Coster et al. 2003; Hendrick, Bell et al. 2009), although as yet there is not a standardised method to analyse accelerometry data and to allow direct comparisons between different monitors across studies.

The use of activity monitors to measure continual movement allows more reliable estimation of daily and weekly fluctuations (variance) in PA levels, which is essential for the design, analysis, and interpretation of PA and health-related studies (Matthews, Ainsworth et al. 2002). Evaluation of the variance in PA measurement is vital for estimating the number of days required to reliably calculate activity levels in a free-living population (Baranowski, Smith et al. 1999). Therefore it is important to investigate variance measures of activity for each specific monitor to estimate days of PA measurement needed to detect change in activity status within both healthy populations and in populations of particular interest (Hertzog, Nieveen et al. 2007).

2.6 Measurement of the variance of activity in free living

The amount of variance and variability in PA measurements within a free-living population is dependent upon a number of factors. These include the types, frequency, and patterns of activity (Levin, Jacobs et al. 1999); gender and age of the participants (Matthews, Hebert et al. 2001); the activity output and type of measurement tool employed (Coleman and Epstein 1998; Matthews, Hebert et al. 2001); and, the amount of error in the measurement system (Baranowski, Smith et al. 1999). Assessing the contribution of within and between individual variance, and how this varies with the number of days of monitoring, is essential when trying to determine the number of days of measurement required to reliably estimate PA, and any change in PA behaviour over time (Baranowski, Smith et al. 1999). Consequently, a repeated measurement design has been commonly employed to assess for changes in PA over time in both healthy adults (Peterson, Yates et al. 2005; Hertzog, Nieveen et al. 2007) and patient populations (Bousema, Verbunt et al. 2007), as it allows for the assessment of how much

within and between individual daily, weekly and monthly fluctuations contribute to activity variation.

Variance and fluctuations in PA within normal free living (Matthews, Ainsworth et al. 2002; Joosen, Gielen et al. 2005), and debate over the validity of the PA measurement tools and differences in sampling time frame (Baranowski and de Moor 2000; Trost, Pate et al. 2000), mean that consensus for an optimal design to measure free living PA levels has not been established. Current recommendations indicate a repeated measure design using an objective measure of activity provides the most accurate method of estimating PA in free living (Levin, Jacobs et al. 1999). The use of both activity monitors and questionnaires also appears to improve analytical procedures and provide a multifaceted way of investigating PA (Janz 2006). It is suggested that the use of both measures provides a greater depth and understanding of the various dimensions of free living activity (Ken-Dror, Lerman et al. 2005). Consequently, longitudinal research is recommended to explore activity behaviours over time and the potential interactions of activity on health-related outcomes. Further discussion and estimation of variance in PA measurement of the RT3 in free living is provided in Chapter IV.

2.7 Accelerometers as measure of free living activity

Accelerometers have been frequently used as objective measures of PA in a range of populations and occupational settings (Busser, De Korte et al. 1998; Estill, MacDonald et al. 2000; Steele, Holt et al. 2000; Hertzog, Nieveen et al. 2007; Cuthill, Fitzpatrick et al. 2008; Sloane, Snyder et al. 2009). They have also been used to assess PA of people with musculoskeletal disorders, including those with LBP (Verbunt, Sieben et al. 2005; Ryan, Grant et al. 2009). While uniaxial accelerometers have also been used extensively to measure and quantify PA within both normal and patient populations (Kumahara, Schutz et al. 2004), triaxial accelerometers have been shown to better capture fluctuations and dimensions of activity and arguably provide more valid and reliable measures (Ng and Kent-Braun 1997; Powell, Jones et al. 2003; Steele, Belza et al. 2003; Neumann, Friedmann et al. 2004; Rowlands, Thomas et al. 2004; Chu, McManus et al. 2007). In support of these findings, employment of all three axes of the RT3 triaxial accelerometer and the Tracmor triaxial accelerometer better predicted EE when compared to using only a single axis in a controlled laboratory setting (Howe, Staudenmayer et al. 2009). Triaxial accelerometry was also found to better estimate total EE in an elderly population when compared to a uniaxial

accelerometer (Yamada, Yokoyama et al. 2008). Uniaxial accelerometry is also underestimated increasing movement and speed on a treadmill when compared to the RT3 triaxial accelerometer across a range of walking and running speeds within a normal healthy population. These findings may potentially be due to frequency dependent filtering and assessment of acceleration in the vertical plane by the uniaxial monitor (Rowlands, Stone et al. 2007). The authors also suggested that the RT3 triaxial accelerometer output across the three axes more strongly related to speed due to the increase in horizontal accelerations at higher speeds (Rowlands, Stone et al. 2007). Thus, triaxial accelerometers have been utilised to better capture the various dimensions of activity in free living (Warren, Ekelund et al. 2010).

Numerous triaxial activity monitors have been employed and validated for use in research to measure activity in free living (Levine, Baukol et al. 2001; Terrier, Aminian et al. 2001; Yang, Chen et al. 2007; Rothney, Schaefer et al. 2008). The majority are waist mounted, which the participant wears on a belt to record movement in daily living. The RT3 (StayHealthy, Inc., Monrovia, CA) is a waist worn triaxial accelerometer which is in widespread use and has been researched extensively for measurement of PA in free living (Steele and Mummery 2003; Neumann, Friedmann et al. 2004; Chu, McManus et al. 2007; Hendrick, Bell et al. 2009). The RT3 has also been employed in recent research investigations within the Centre for Physiotherapy Research at the University of Otago (Hale, Williams et al. 2007; Hale, Pal et al. 2008). The availability and support within the research centre coupled with an extensive research base supporting its use for free living activity measurement made it a pragmatic choice as the objective measure in this study. The following literature details and reviews the evidence for use of the RT3 as a measure of free living activity for longitudinal research within LBP populations.

2.7.1 The RT3 triaxial accelerometer

The RT3 is a small (71 X 56 X 28mm), lightweight (65.2g), battery (AAA) powered tool used for measuring the physical activity levels of people. The RT3 has a dynamic range of 0.05-2g and is sensitive to movement in the 2-10Hz range (Powell, Jones et al. 2003); these frequencies are comparable to frequencies at the waist whilst performing daily activities (Krasnoff, Kohn et al. 2008). The sensor is a triaxial accelerometer sensitive to movement along three orthogonal axes (X, Y, and Z) which represent vertical, anterioposterior, and mediolateral motion, respectively. The acceleration signal is converted to a digital

representation and then processed to record an “activity count” which is stored in the memory for ultimate extraction. The device has four different modes of action: mode 1 samples and stores activity counts on individual axes at one second epochs; mode 2 samples and stores the combined vector values at one second epochs. Vector Magnitude (VM) is derived from ([X2 + Y2 + Z2] 0.5), a measure which represents the square root of the sum of squared values of each individual axes. Mode 3 samples and stores accumulated activity counts on individual axes over one-minute epochs; mode 4 samples and stores accumulated VM activity counts every second and provides an average over the one-minute epoch. The RT3 output also includes activity calories and total calories for each minute of activity calculated by proprietary equations from the VM activity counts, as well as age, weight, and height measurements of the individual.

2.7.2 Reliability and validity of the RT3

Validation and reliability of the RT3 has been assessed under a number of laboratory based conditions within adults, including: walking and running at standardised speeds on a treadmill (Powell and Rowlands 2004; Rowlands, Thomas et al. 2004; Rowlands, Stone et al. 2007; Stone, Esliger et al. 2007; Hussey, Bennett et al. 2009); and also employing a shaker table (Powell, Jones et al. 2003; Krasnoff, Kohn et al. 2008); assessing various mobility tasks (Hale, Williams et al. 2007); and during structured activities (Rothney, Schaefer et al. 2008) in the laboratory. The focus of the current review was on studies which had assessed validity and reliability of the RT3 in the lab on adults; results are detailed in Table 2-1.

2.7.3 Lab-based reliability testing of the RT3

The assessment of reliability on a standardised testing on a shaker table allows direct comparisons between trials to a standardised force and frequency without influence of human variability in movement, and thus provides a more valid measure of actual monitor reliability to measure and record movement at particular forces and frequencies. However, human reliability studies theoretically allow a better estimate of the predicted reliability when assessing activity in free living environment, as it is assesses the monitor relative to the person; this however introduces potential difficulties, even for standardised laboratory activities, in that human movement about the waist and pelvis during activities of daily living shows normal variation both within the same individual for a specific task and between individuals (Dingwell and Marin 2006), and such variability can potentiality increase in patients with disability (Hale, Williams et al. 2007). The majority of studies investigating reliability of the RT3 on a shaker table, employing a range of testing frequencies, reported

good intra-unit reliability (ICC = 0.99) and a coefficient of variation (CV) which ranged from 0.29-1.81 % (Powell, Jones et al. 2003; Dingwell and Marin 2006; Krasnoff, Kohn et al. 2008). Importantly, in one study, the shaker table analyses were also able to also identify four RT3 monitors as outliers (Powell, Jones et al. 2003). Higher levels of RT3 inter-instrument reliability where found over a relatively low frequency range (1.5-2.5Hz) with a wide CV of 42.9 % (Esliger and Tremblay 2006). All studies reported relatively poor inter-monitor reliability (CV range 13.1– 105.3) which was frequency dependant, with poorer reliability at the lower frequency range (Powell, Jones et al. 2003), and also varied reliability depending upon axes of measurement (Krasnoff, Kohn et al. 2008). These results have implications for lab-based experimentation of RT3 reliability to test how much unit reliability alters dependent upon human movement.

Studies on participants in lab-based experiments also show differences in inter- and intra-monitor reliability. Intra-monitor reliability testing of two RT3s worn on the right and left hip whilst walking on a treadmill at increasing speeds ranged from moderate to good (ICC = 0.51-0.94) in nine young healthy males (Rowlands, Stone et al 2007). The study also showed that there was less variability in RT3 VM with increasing epoch time. A study of reliability in specific mobility tasks within a small cohort of middle aged participants with Multiple Sclerosis and age matched controls found monitor reliability was task dependent, and also varied between the disabled and non-disabled group (Hale, Williams et al 2007). Lower and more variable levels of intra-monitor reliability were found in the “timed up and go” test in both groups (ICC = 0.5 and -0.04) when compared to the 5 minute walk test (ICC = 0.64/0.65). These results suggest that reliability is both a function of the participant and the task, whereby less standardised tasks, which potentially allow more variation in movement, show poorer levels of reliability.

Intra-monitor variability was also found to increase with increased speed on a treadmill (21%-82%) when assessing reliability within one healthy female employing four RT3 machines attached to the left or right waist (Powell and Rowlands 2004). Intra-monitor CV was low in standard walking activities (< 6%), however, increased to 8-25% during sit-stand. A number of studies have assessed test re-test reliability of the RT3 on a treadmill over two time points at specified speeds (Powell and Rowlands 2004; Krasnoff, Kohn et al. 2008). Hendrick et al. (2010) found no difference in VM counts between ground and treadmill walking at brisk and normal walking pace at two time points, one week apart, in a group of normal healthy participants. Although wide individual variability was found over each session

in both “normal” and brisk walking on the two surfaces, no overall group difference was found between the two walking speeds on either surface over the two sessions. Rowlands et al. (2007) also reported no difference in RT3 output between trials when testing nine male runners wearing 2 RT3 monitors on a treadmill at incremental speeds from 4km/hr to 18 km/hr. Speed dependent variability increased when investigating RT3 output from a treadmill compared to level ground walking (Vanhelst, Zunquin et al. 2009). In each of these studies, participants wore the same RT3 units at both sessions, demonstrating that the RT3 is a reliable measure of walking intensity over time on both level ground and treadmill walking. However, the results also found large individual differences between sessions, and reliability was comparatively poorer at higher walking speeds, running, and unstructured activities. The higher levels of intra-monitor reliability on machine testing tend to suggest that the lower reliability in lab-based experiments is largely a product of the variation in human movement within the same subject for a given task. Such variability in movement would be expected to increase as movement intensity increases, and also in unstructured activities compared to more standardised walking activities.

Overall these results show that the RT3 demonstrates relatively high levels of intra-monitor reliability, while inter-monitor reliability is lower and more variable and appears to be frequency and velocity dependent. The differences in reliability reported for the RT3 may potentially be due to a number of factors including the numbers of RT3 tested; site of attachment; and differences in the age and health of the participants. Differences in trial procedures make comparisons difficult; however, a consistent feature of the results is that intramonitor reliability is moderate to good and consistently higher than intermonitor reliability, which demonstrates much greater variability. Therefore recommendations from this review for longitudinal studies are that each subject should wear the same device on repeat testing, and also highlight the need to perform standardised testing procedures to identity potential malfunctioning RT3 machines before undertaking longitudinal research. It could also be argued that the requirement for pre-monitor testing in patients with disability is also carried out on such individuals as it is known that variability in movement may be more common in this group. Further research on optimal pre-testing of machines is required to better evaluate how reliability is affected in everyday activities and in particular in participants with disability.

2.7.4 Lab-based validity testing of the RT3

2.7.4.1 Content validity

The content and construct validity of the RT3 as a measure of activity EE has been assessed by investigating its ability to measure and differentiate activities across a range of activities and tasks in the laboratory setting, compared to gold standard measurements of EE including DLW and respiratory gas analysis (King, Torres et al. 2004; Rothney, Schaefer et al. 2008; Howe, Staudenmayer et al. 2009). A study which assessed the correlation between RT3 VM counts and respiratory gas analysis activity EE found that VM counts correlated significantly with oxygen consumption in both boys and young males over four treadmill walking speeds and three non-regulated conditions (Rowlands, Thomas et al. 2004). Group differences for activity cut off points for RT3 VM counts were developed which were able to differentiate moderate and vigorous activities in the two groups. However, King et al. 2004 reported that the RT3 overestimated total EE at all treadmill speeds in a young healthy population ($p < 0.001$), and correlations between RT3 VM to indirect calorimetric (IC) ranged from only moderate to poor across the activities (0.02- 0.73). In a further study, the RT3 was found to significantly underestimate total activity EE; total time spent in light and moderate activities, and overestimate sedentary activities within a group of healthy adults employing the proprietary equation to convert RT3 VM counts into measures of activity EE (kcals/min) (Rothney, Schaefer et al. 2008). Subjects completed an overnight stay in a room calorimeter while wearing the RT3 and then engaged in two structured activities of increasing intensity. The authors reported that a derived Chen regression equation for the RT3 was the best fit to predict activity EE. Comparatively, the RT3 was also the most error prone of the tested accelerometers (Actigraph and Actical) for distinguishing between light and moderate activities. Howe et al. 2009 reported that the RT3 underestimated activity EE by 8.4% compared to a metabolic analyser across a range of treadmill speeds and activities of daily living within a large healthy adult population. The underestimation was most marked in activities of daily living (34%) and particularly in activities with greater upper arm movement. There was a direct correlation found between the degree in under-estimation of activity EE by the RT3 and increasing activity intensity. These results show that content validity of the RT3 as a measure of EE under laboratory conditions within healthy adults is inconsistent, and that much of the variability is based upon increased activity intensity and types of activity (Howe, Staudenmayer et al. 2009) and potential errors in the proprietary equation employed to convert RT3 VM counts into activity EE (kcals/min) (Rothney,

Schaefer et al. 2008). Thus, the RT3 has only moderate content validity as a measure of EE in these laboratory based tasks.

2.7.4.2 Concurrent and construct validity of the RT3

The concurrent validity of the RT3 to measure activity EE has been investigated in the lab by comparing the ability of the RT3 to predict EE compared to uniaxial and other triaxial accelerometers (King, Torres et al. 2004; Rowlands, Stone et al. 2007). King et al. (2004) investigated the concurrent validity of the RT3 in comparison to four other commercially available accelerometers over a range of laboratory-based tasks, and found no significant difference in mean EE recorded by any of the monitors ($p < 0.05$) at any treadmill speed. RT3 VM counts maintained a linear relationship with speed ($r = 0.96$, $p < 0.001$), however Actigraph counts peaked at 10 km/h and declined thereafter ($r = 0.02$, $p > 0.05$) (Rowlands, Stone et al. 2007). Comparatively, the RT3 VM was more strongly related to speed than the Actigraph, and particularly for differentiating higher speeds.

Aspects of the construct validity of the RT3 have been investigated by assessing the ability of the RT3 to accurately capture and differentiate various standardised walking speeds (King, Torres et al. 2004; Rowlands, Stone et al. 2007), and activities of daily living (Samakudas et al 2008). Overall, RT3 output was found to be linearly related to speed and step frequency in a group of healthy adults walking at standardised speeds on a treadmill (Rowlands, Stone et al. 2007). These findings are consistent with previous research showing that the RT3 is sensitive to changes in walking speeds on a treadmill (King, Torres et al. 2004; Rowlands, Thomas et al. 2004). A recent study found that RT3 output equally distinguished between participants' normal and brisk walking speeds on ground and level surfaces over two time points within a cohort of healthy adults (Hendrick. Boyd et al. 2010). In support of these findings, a similar study reported of RT3 VM data comparing walking and running conditions at specified speeds of 4km/hr, 6km/hr, 8km/hr, and 10km/hr on a single occasion within a healthy population (Vanhelst, Zunquin et al. 2009). The RT3 also demonstrated good construct validity to differentiate activity intensities with a high correlation of RT3 VM with observational data reported in visually impaired children ($r = 0.89$, $p < .001$) (Kozub, Oh et al. 2005).

Despite issues of between-monitor reliability, the RT3 appears to demonstrate reasonable construct and concurrent validity in laboratory-based settings. The RT3 has reasonable construct validity as a comparative measure of differentiating walking intensity in normal

healthy populations on both ground and treadmill surfaces. The results also showed that RT3 data can equally distinguish walking intensity on both surfaces within healthy populations. However, further research is required to investigate the construct validity of the RT3 in patients with disability.

Table 2-1 Studies investigating in a laboratory setting validity and reliability of the RT3 in adult populations

Authors	Participants	RT3 measures of activity	Tasks performed	Results
Rowlands (2004) et al	19 boys (mean age 9.5) and 15 men (20.7)	1 RT3 used on all participants and Tritrac Heart rate monitor and Gas Analysis (SvO2)	4 treadmill speeds and 3 non regulated conditions 4 minutes each	Correlational analysis found significant differences between both monitors for each activity ($p < 0.05$) Men- RT3 VM to SvO2 = 0.851, 0.792 on treadmill and 0.885 in non regulated activities Group differences for activity cut off points (Men 3 METS = 984), Men 6 METS = 2340) and non regulated activities (3 METS = 732, 6 METS = 1798)
Powell and Rowlands (2004)	One person 24 year old female	8 RT3 machines 4 RT3 machines attached to right or left hip on each trial	Two trials (2 days apart) of 6 activities Rest, walking (4 and 6 kmphr4 48 ,) running (8 and 10kmph) and repeated sit to stand Each activity was performed for 12 minutes	At the two trials all activities were significantly different from each other with the exception of rest and sit-stand with a percentage not differentiating between trial 1 and 2 (16% and 34%) Within activities there was no significant differences between monitors at rest, 4kmph or sit-stand, however as the intensity increased the inter-monitor variability increased (21%-82%) with 21% significantly different on trial 1 and 18% on trial 2. No monitors were significantly different between trials The authors highlighted significant speed dependent inter-monitor differences indicating the need to match the same RT3 to the same individual
Powell and Jones (2003)	Vibration table	23 RT3 States that the accelerometers used in the RT3	Vibration at 2.1, 5.1 and 10.2Hz and each RT3 placed in the jig at 3 alignments to record the X,Y and Z axes	High inter-monitor reliability (ICC 0.99) on each axis across each frequency The variability of RT3 VM CV% at 2.1Hz ranged from 22.6-38.5, lower variability at the 5.1Hz and 10.2Hz reported The results showed good inter-monitor reliability but variable intra-monitor reliability which was frequency dependent with the highest variability noted at 2.1Hz
Esliger and Tremblay (2006)	Hydraulic shaker table 6 different testing	5 RT3, Actical and Actigraph monitors	6 different conditions and collected data for 7 minutes Vibration range - force 0.5-1.25g,	RT3 inter-instrument CV 42.9% and intra-instrument CV ranged from 13-106.9%. These results found variable inter-monitor reliability when compared to the Actical and Actigraph and vary large intra-instrument variability

Authors	Participants	RT3 measures of activity	Tasks performed	Results
	conditions		with freq range from 1.5-2.5Hz	
King et al (2004)	21 (10 men, 11 women)	RT3, CSA, Tritrac, Biotrainer, and SenseWear armband. RMR (respiratory gas analysis) Peak Oxygen Uptake Test on treadmill	Treadmill walking at 53, 80, and 107 m per minute, treadmill running at 134, 161, and 188 and 214 m per minute in sequence for 10mins with 2 minute rest period	No significant differences in monitor output for the RT3 in (L) and (R) hip placement ($p = 0.16$) All RT3 indicators increased with each treadmill speed with the increase from 188-214 attenuated The RT3 overestimated total EE at all treadmill speeds ($p < 0.001$) Gender had a significant effect on PAEE and TEE of RT3. Correlations of RT3 VM ranged (-0.49- 0.22) for PAEE (0.02- 0.73), TEE (0.18-0.75)
Rowlands et al (2007)	Nine male runners (23.1 SD 3.4 years)	Participants wore 2 RT3 accelerometers and 2 Yamex pedometers (one each positioned above the hip) and 2 Actigraph over each hip.	Treadmill walking for 60seconds at 4, 5, 6 (km/ph) and running at 8, 10, 12, 14, 16 and 18 (km/ph) and for 30 seconds at 20, 22, 24, 26 (km/ph) Participants returned 1 month later to repeat the procedure.	Reliability of RT3 VM ICC ranged from 0.51-0.94 Relationships with speed, step frequency and monitor output showed the poorest reliability in midrange speeds and for speeds at end of range Intra-monitor variability- Two-way speed and epoch interactions were evident for the RT3 ($p < 0.01$). Post-hoc Turkey tests showed that the CV of the 1sec epoch was consistently higher than the 5, 10 and 15 second epochs ($p < 0.05$) RT3 output was linearly related to speed and step frequency (compared to the uni-axial accelerometer and the pedometer).
Hale et al (2007)	10 people with MS (49 years) and 10 non-disabled people	1 RT3 worn on the centre of the lower back	3 mobility tasks. 1. 5 minute walk test. 2. The timed up and go. 3. A stair climbing task	ICC values for the RT3 - MS/controls ICC ranged from 0.64/0.65 5 minute walk test ICC ranged from 0.5/-0.04 Timed up and go ICC ranged from 0.76/0.39 Reliability of the monitors was shown to be dependent on the observed group inconsistencies in motor task performance
Samukadas et al (2008)	20 independently mobile subjects over 65	RT3 (2) clipped to the subject's waistband ant to the hip. Same	6 minutes standing. 6 minutes sitting (no talking or moving). 6 minutes sitting. 6 mins walking (6MW) performed in a corridor 25m long. 6	There were substantial intra-individual differences between right and left sided counts for all tasks except walking ($p < 0.05$). A cut-off value of approx 250 VM counts/min discriminated between sedentary and

Authors	Participants	RT3 measures of activity	Tasks performed	Results
	attending the Medicine for Elderly Services. 5 young healthy volunteers (staff members) aged below 50 5 mobile from each category chosen	accelerometers used for each participant. 7 day mode used (1 minute epoch)	mins step climbing (3 steps) (resting, sitting, and standing all referred to as sedentary)	non-sedentary tasks. This cut-off value held for both the young and old. No clear demarcation was found between resting, sitting and standing in older participants. Counts for the 6 minute walk tests were significantly higher for young participants ($p < 0.01$). There was no significant difference in counts/meter walked between the 5 groups tested ($p > 0.05$).
Rothney et al (2008)	85 healthy adults (37 men, 48 women) between 18-70	Actigraph, Actical and RT3 (on a belt on the right hip)	Each subject completed an overnight stay the room calorimeter while wearing the 3 monitors. and engaged in 2 structured activity intervals (10 mins and 10mins rest) Body composition calculated using dual energy X-ray absorptiometry	The RT3 proprietary equation significantly underestimated total PA as well as total time spent in light and moderate activities and overestimated sedentary activities ($p < 0.01$) The proprietary equation for the RT3 for distinguishing between light and moderate activities was generally the most error prone for all accelerometers
Krasnoff et al (2008)	No participants	22 RT3 units were tested for 24 hours (each test performed for 3 consecutive 24 hour periods. Mode 3 was used (1 minute on x,y and z)	Used a shaker table – HS 260 Control Reciprocating Shaker (0-300 RPM) Tested at 2 speeds 150 and 275 RPM equivalent to 2.5Hz and 4.6Hz with amplitudes of 0.35g and 0.64g.	The average within unit SD of VM counts ranged from 7.3 to 38counts/min The CV for RT3 VM counts ranged from 0.29-1.81% and the average repeatability coefficient ranged from 19.98 to 105.36 counts/min (5% of each trial's 3-day mean) Inter-unit reliability for RT3 VM counts- CV's ranged from 9.5%-34.7% The highest CV was found at 150 RPM in the medio-lateral direction. The ICC's across the 4 experimental conditions ranged from 0.00 to 0.042. Repeatability coefficient ranged from 505 to 1516 counts/min. A significant differences among the 22 units for all trials ($p < 0.05$)
Vanhelst et al (2009)	50 healthy sports science	RT3 – epoch 1 minute fixed to a	Walking and running at 4, 6, 8 and 10 km/h (3% treadmill incline).	4kmph – mean diff - 41 VM units, 6kmph mean diff - 68 VM units, 8kmph mean difference 19 VM units, 10 km/h mean diff 39 VM units.

Authors	Participants	RT3 measures of activity	Tasks performed	Results
	students (35 males and 15 females, Age 21 (mean) familiar with treadmill walking	belt and worn on the right hip. Used data from minutes 3-10 (discarded 1-2). Heart rate using the Polar device	Participants ran around a border of a field (40-20m) to ensure correct velocity the speed was fixed using markers every 29m around the handball field with chronometer and oral signals	Bland-Altman Plots Limits of Agreement for VM counts- 4kmph – -235 to 152, 6kmph -328 to 190, 8kmph -360-398, 10 km/ph -349 - 427
Howe et al (2009)	Healthy 20-60 year olds 212 subjects	RT3 secured on non-dominant hip on 1 sec epoch	RMR detected using metabolic analyzer) Treadmill – six bouts of up to 7 mins at speeds of 1.34, 1.56, and 2.23m/sec at 0% and 3% grades with 4mins of rests Activities of daily living 7mins ascending and descending stairs, moving a 4.5kg box and 2 randomly selected activities from a menu of 14 household and sport-related ADL TEE – measured with a portable metabolic analyzer.	For all activities the difference between AEE and RT3 AEE was significantly different from zero ($p < 0.05$) with RT3 AEE underestimating AEE by 8.4% RT3 over-estimated AEE on the Treadmill by 9%and underestimated ADL by 34%. Strong relationship between RT 3AEE and VM counts ($r^2 = 0.89$, $p < 0.01$))

ADL Activities of daily living; AEE Activity energy expenditure; METS Metabolic equivalents, VM Vector magnitude, SvO2 Oxygen saturation, EE Energy expenditure, PAEE Physical activity energy expenditure, TEE Total energy expenditure; RMR Resting metabolic rate; CV Coefficient of variation; RPM Revolutions per minute

2.7.5 Field studies using the RT3

The RT3 monitor has been extensively utilised in both normal and patient populations. It has been used as a primary outcome measure of both activity (Peterson, Yates et al. 2005) and EE (Buchheit, Simon et al. 2005; Padilla, Wallace et al. 2005) in "normal' populations and patient populations (Neumann, Friedmann et al. 2004; Majchrzak, Pupim et al. 2005; Bousema, Verbunt et al. 2007). The following section reviews the evidence for the RT3 in field study research to measure PA in free living within healthy adult populations. Results are summarised in Table 2-2.

2.7.6 Normative research

Research studies have investigated the content validity of the RT3 as a measure of free living EE (Matton, Wijndaele et al. 2007), and convergent validity of the RT3 compared to other activity monitors and pedometers (DeVoe and Dalleck 2001; DeVoe, Gotshall et al. 2003), and also as a validation instrument for activity questionnaires in free living (Matton, Wijndaele et al. 2007).

Validity of the RT3 as a measure of free living PA has been investigated by assessing and comparing the ability of the RT3 to measure activity in free living compared to other objective measures of activity. The convergent validity of the RT3 was compared to a heart rate monitor, pedometer, uniaxial accelerometer, and a questionnaire in 49 ethnic Chinese (30 men, 19 women), aged 15-55 years (Macfarlane, Lee et al. 2006). Spearman correlation coefficients were low to moderate ($r = 0.2\text{-}0.5$) across most measures of activity with wide variation across the different instruments, with two- to four-fold differences in mean durations of activity often seen. However, good agreement between the recall questionnaire (International Physical Activity Questionnaire) and the two accelerometers was found. The RT3 was compared to the TriTrac in a single subject design on a 6-day backpacking expedition. The authors reported an overall moderate correlation between RT3 VM counts and the R3D ($r = .75$, $p < .001$), with the overall calculated bias and standard deviation of the differences across all six days of measurement estimated at 235+/-436 VM activity counts (DeVoe 2004). Thus, the RT3 demonstrates reasonable convergent validity compared to another triaxial measure of activity but much lower correlation with other objective measures of PA.

Use of the RT3 as a validation instrument for activity questionnaires has been investigated in a range of patient populations and recall instruments. Reasonably good concurrent validity was found for RT3 EE (kcals) against the Flemish Physical Activity Computerized Questionnaire in men (r = 0.74-0.99) and in women (r = 0.71-0.99) across a range of activities in a group of healthy adults and retired people (Matton, Wijndaele et al. 2007). A significant interaction ($p < .001$) between EE measured with an RT3 and VO2 ($p < .001$), and high correlations (r = 0.89 to 0 .99) between the 7D-PAR and the RT3 was found in a group of women with low to moderate exercise risk measured at baseline and at 6 and 12 weeks after an activity intervention (Peterson, Yates et al. 2005). Thus correlations between the RT3 and recall instruments are a product of both the questionnaire and the population under investigation, with higher correlation found in participants with lower levels of activity and potentially less variability in their activity levels over time.

Content validly of the RT3 was investigated in a group of healthy New Zealand adults (20 women, 16 men) (Maddison, Jiang et al. 2009). The correlation between DLW and RT3 VM was low ($r = 0.32$, $p < 0.05$), and the RT3 underestimated total EE by 4% and activity EE by 14%. They reported that compared to DLW the RT3 underestimated total EE by 539 kJ (4%) and activity EE by 485 KJ (14%) with good agreement between the two measures but greater variability at lower activity levels. The variance in activity EE was largely explained by sex, fat (kg) and resting metabolic rate (RMR) (47%), while RT3 VM counts explained a further 7%. A review of free living studies found that the relationship between DLW and triaxial accelerometry output often show variable correlations (Plasqui and Westerterp 2007), driven by subject characteristics such as body weight. Thus, the research shows that triaxial accelerometry has relatively poor validity as a measure of free living EE.

Overall the RT3 appears to have reasonable validity as a measure of free living activity within normal populations; however RT3 measurements of EE are more problematic due to the fact that EE is largely driven by factors other than movement, and correlations between RT3 EE and ‘gold-standard” measures are highly variable. A number of studies also reported technical and utility issues with the RT3 with consequent data loss in longitudinal free living research (Matton, Wijndaele et al. 2007; Chen, Jerome et al. 2009; Hollowell, Willis et al. 2009). Issues of utility and measurement error of the RT3 for field measurement of activity will be further discussed in Chapter V.

2.7.7 Clinical research

The RT3 has been employed as a measure of PA and EE in a range of patient populations including LBP (Bousema, Verbunt et al. 2007), post surgical patients (Neumann, Friedmann et al. 2004), psychiatric illness (Soundy, Taylor et al. 2007), and neurological conditions (Hale, Pal et al. 2008). The RT3 has also been extensively employed as the outcome measure of PA or EE in patient populations (Neumann, Friedmann et al. 2004; Majchrzak, Pupim et al. 2005; Verbunt, Sieben et al. 2005; Hertzog, Nieveen et al. 2007) (Table 2-2).

2.7.7.1 Reliability of the RT3 in clinical field studies

Reliability of the RT3 was investigated in an elderly population of patients (56 males and 9 females) aged between 64 and 86 years, and recruited from hospitals prior to discharge after a Coronary Artery Bypass Graft (Hertzog, Nieveen et al. 2007). Participants wore an RT3 monitor for 3 days (including one weekend day) clipped to the waist-band and worn at 3 weeks, 6 weeks and 3 months post-surgery (Hertzog, Nieveen et al. 2007). The authors reported that a total of 51 units were used across the three measurements, with 34-38 different units at each time point. Over the data collection period, 35 units had to be returned for cleaning and 20 needed to be replaced, and therefore only 37 participants could be assigned the same RT3 unit over the measurement period. Despite these utility issues with the RT3, the reported reliability was good (ICC values ranged from 0.85-0.97). Similar high levels of test re-test reliability for the RT3 (ICC 7-day range 0.68-0.85, 3-day range 0.54-0.9) were reported within a mixed sample of elderly patients with neurological disorders and healthy sedentary controls (Hale, Pal et al. 2008). Patients wore the RT3 for 7 days on two occasions at 6 weeks apart. Although utility issues were raised, including the RT3 being uncomfortable in centre of the low back and a worry that it would fall off, the average number of hours of wear was relatively high (11hours/day) and no subject included in the analysis had less than 10 hours/day. In a separate study, there were no significant differences in the repeatability of accelerometer readings between a group with pulmonary disease and a control group (repeatability coefficient of 11.2% [4.6%] and 8.5% [4.7%], respectively), demonstrating good reliability in both groups employing two measurement points 5 weeks apart (Lores, Garcia-Rio et al. 2006). These results indicate that repeat measures of RT3 data in free living are moderately reliable between sessions and across various patient groups. However, the studies also reported utility issues in terms of machine malfunction and loss which may affect the reliability of the RT3 for longitudinal repeated measurement of activity

2.7.7.2 Validity of the RT3 in clinical field studies

Validity of the RT3 in free living has been investigated by assessing the construct validity against a number of activity questionnaires within various population groups (Dubbert, White et al. 2006; Hertzog, Nieveen et al. 2007; Orrell, Doherty et al. 2007) and against DLW (Jacobi, Perrin et al. 2007). Correlation between RT3 VM and total EE from the 7D-PAR questionnaire were moderate (r = 0.43), and correlations at moderate activity (r = 0.16) and vigorous activity levels (r = 0.08) were significantly lower in a small group of participants with psychiatric illnesses (Soundy, Taylor et al. 2007). Hertzog et al. 2007 reported moderate to good correlations between RT3 EE and the 7D-PAR (r = 0.72-0.57) in 65 elderly patients, and lower correlations at moderate or higher activity levels (r = 0.24-0.43). Fair agreement between total minutes of PA from the International Physical Activity Questionnaire (IPAQ) and RT3-estimated MET min/wk (Spearman's p= 0.37) was also found over 7 days of monitoring in a population with diagnosed schizophrenia (Faulkner, Cohn et al. 2006). A further study investigated the correlation between RT3 EE and two recall questionnaires in a small cohort of community-dwelling veteran patients (n = 20), most with psychotic disorders and substance abuse in remission. The RT3 was worn for 3 days and RT3 VM activity counts transformed into kcals/hr (from the proprietary equation). Participants completed a Healthy Activities Model Program for Seniors (CHAMPS) Past Week Recall (PWR) questionnaire. Correlations between RT3 EE and the CHAMPS PWR minutes of walking were low (r = 0.24) and estimates of kcals/hr from the RT3 showed moderate correlation with the PWR minutes of moderate activity (r = 0.4). While another study reported only fair agreement between total minutes of PA from the IPAQ and RT3 estimated EE (Spearman's p = 0.37). The correlation was not significant in terms of total IPAQ MET mins/week (p = 0.33). Two further studies reported low and variable correlations between the RT3 and activity questionnaires which were activity dependent in an elderly population and a group with psychotic illness (Dubbert, White et al. 2006; Orrell, Doherty et al. 2007). These results show low to moderate correlation between the RT3 and activity questionnaires across a range of patient populations in free living and that correlations are activity dependent with moderate and vigorous activity demonstrating lower correlations.

A recent review identified that few instruments have been validated as measure of free living PA (Cervantes and Porretta 2010). These results demonstrate the low and variable correlation between objective and non-objective measures highlighting that each potentially measures different constructs of activity and thus the authors suggest that it is important to include both in measurement of PA in free living research. Content validity of the RT3 was assessed in 13

overweight and obese patients over a 14 day measurement period. Measurements of EE by the RT3 significantly correlated with EE from DLW ($r = 0.55$, $p < 0.05$) (Jacobi, Perrin et al. 2007). Correcting the PAEE by substituting the RMR from IC improved the correlation ($r = 0.67$). Thus, the RT3 demonstrates reasonable validity as a measure of free living activity, although further research and validation in specific populations is required.

2.7.8 Overview of RT3 measurement in patients with disability

The recorded number of days of RT3 wear varied in the studies from 3 days (Hertzog, Nieveen et al. 2007) to 14 days (Hecht, Ma et al. 2009), although 7 days of measurement was the most common period of time (Neumann, Friedmann et al. 2004; Faulkner, Cohn et al. 2006; Lores, Garcia-Rio et al. 2006; Sloane, Snyder et al. 2009). The RT3 was most commonly clipped to waist (Hertzog, Nieveen et al. 2007; Klassen, Schachter et al. 2008; Sloane, Snyder et al. 2009) for free living activity measurement, or worn at the centre the lower back (Hale, Pal et al. 2008). The output measures from the RT3 were expressed either as VM counts (Hale, Pal et al. 2008; Klassen, Schachter et al. 2008; Hecht, Ma et al. 2009), or as a measure of EE calculated from the proprietary equation (Neumann, Friedmann et al. 2004; Dubbert, White et al. 2006; Jacobi, Perrin et al. 2007). As previously outlined, a number of studies reported utility issues with the RT3 including loss of data due to failure of the RT3 or recording less days than the inclusion criteria (Bousema, Verbunt et al. 2007; Hertzog, Nieveen et al. 2007), loss of data due to water immersion (Orrell, Doherty et al. 2007), and battery failure of the RT3 (Nguyen, Steele et al. 2006). A number of studies assessed activity with a repeated measures design for assessing change in activity; the relationship between PA outcome measures over time and the relationship between health outcome measures and PA (Lores, Garcia-Rio et al. 2006; Bousema, Verbunt et al. 2007; Hertzog, Nieveen et al. 2007; Sloane, Snyder et al. 2009); however the majority of studies employed only one measurement point. Thus, no standardised protocol for evaluating activity with the RT3 exists, with differences in the days of measurement, PA outcome employed, and number of measurement points across studies. Better standardisation of PA measurement protocols including days and amount of measurement and minimising utility issues of the RT3 for free living activity measurement, are required for longitudinal field research.

2.8 Conclusions

In order to better understand potential relationships between activity and health outcomes it is argued that activity measures need to be accurate, valid, and reliable. This review highlighted

the complexities of measuring the various dimensions of free living activity. At present there is no standardised protocol for measuring activity with various measurement instruments; each has potential strengths and weaknesses. This review focused on the examining the validity and reliability of two activity measurement tools: a recall questionnaire (7D-PAR) and a measurement of habitual activity (BPAQ) and more specifically on the RT3 triaxial accelerometer as a measure of free living activity. The RT3 was found to have reasonable validity and reliability for measurement of activity in free living; however, several limitations with both instruments were discussed and recommendations for future longitudinal study made.

The following chapter evaluates the literature relating to physical activity advice and measurement in populations with LBP, briefly examines the aetiology and prognostic factors in LBP research, and evaluates outcome measures for prospective research in LBP.

Table 2-2 Field Studies of the RT3 in Clinical Populations

Authors	Subject	RT3 and physical activity measures	Main purpose	Results
Lores et al (2006)	12 healthy control subjects and 23 patients with stable COPD	RT3 attached to a belt with a clip on mode 4 for 7 days and repeated within 3-5 weeks Activity log	To assess the agreement between different measures of mean daily PA in patients with COPD and controls and to analyse medium term repeatability	No significant differences in medium-term repeatability of accelerometer readings between COPD group and the control group (repeatability coefficient of 11.2% [4.6%] and 8.5% [4.7%], respectively ($p = 0.41$)
Neumann et al (2004)	46 patients (> 60 years) who had recently undergone surgical repair of a hip fracture	RT3 worn for 7 days at the hip. PAEE expressed as output (4 weeks post study intervention)	Comparison of clinical outcomes with standard and high protein diet	PAEE from the RT3 did not differ in the two groups ($p > 0.05$)
Dubbert et al (2006)	20 male community-dwelling veteran patients, most with psychotic disorders and substance abuse in remission.	RT3 worn for at least 3 days (VMU/day) transformed into kcal/hr (EE) 42 item Community Healthy Activities Model Program for Seniors (CHAMPS) Past Week Recall (PWR) questionnaire	To assess feasibility and validity of using standardised self-report and objective measures of physical activity in patients who are mentally ill	Significant correlation between RT3 EE and CHAMPS and PWR minutes of walking ($r = 0.4$ and $r = 0.39$, $p < 0.05$) Estimates of k/cals (EE) from the RT3 showed moderate correlation with the PWR minutes of moderate activity ($r = 0.5$, $p < 0.05$)
Faulkner et al (2005)	35 outpatients with a diagnosis of schizophrenia.	RT3 worn for 7 days on the waist - analysed counts which were greater than 3.3METs/min RT3 data expressed as METS/min/wk Activity Log and IPAQ	To provide preliminary validation of the Short-Form International Physical Activity Questionnaire (IPAQ)	Fair agreement between total minutes of PA from the IPAQ and RT3 (Spearman's $p= 0.37$, $p < 0.05$) No significant correlation with total IPAQ MET mins/week ($p=0.33$, $p = 0.14$) and RT3 EE
Majchrzak et al (2007)	55 patients with chronic haemodialysis (mean age 47 years)	RT3 worn for 7 days with a requirement for at least 5 days of measurement	To examine the correlations between somatic and visceral protein stores and physical activity, physical functioning and dietary intake	Total PA counts were significantly lower on dialysis days when compared with non dialysis days (128,279 +/- 74,009 versus 168,744 +/- 95,168, respectively, $p = .025$). The average PA counts during the 4 hour dialysis time period were significantly lower on dialysis days when compared with non dialysis days (3,086 +/- 3,749 versus 11,070 +/- 7,695, respectively, $p = .001$)

Authors	Subject	RT3 and physical activity measures	Main purpose	Results
Jacobi et al (2007)	Thirteen overweight and obese patients (mean age 38.3 years)	RT3 and TriTrac R3D worn for 14 days Activity log DLW Indirect Calorimerty	To compare two triaxial accelerometers for their ability to produce PAEE in obese subjects in free living	Measurements of PAEE by the RT3 significantly correlated with PAEE (DLW) ($r = 0.55$, $p < 0.05$) Correcting the PAEE by substituting the RMR from indirect Calorimerty improved the correlation ($r = 0.67$)
Bousema et al (2007)	124 Patient with sub-acute low back pain (mean age 47.3 years)	RT3- worn for 7 days. Expressed as Total = counts/day The perceived level of PA decline (PAD) BPAQ and the level of PA in the 1 year prior to pain.	To evaluate the development of disuse in patients with back pain during 1 year after pain onset.	No difference in the PAL change between groups (recovered to non- recovered) ($p = 0.35$) Depression and PAD had a small but significant predictive value for PAL change ($p < 0.05$).
Verbunt et al (2005)	123 patients (66 male and 57 female) with 4-7 weeks of non-specific low back pain (Mean age of 44.1 years)	RT3 worn for 7 days (1 minute counts/minute) Activity = total sum of counts/day Physical activity in daily life after the onset of pain (PAL) used as Physical activity in daily life before the onset of pain (H-PAL) measured with the Baecke (BPAQ)	To evaluate the relationship between activity levels and LBP outcomes	No association between PAL and disability, fear of injury, depression, and pain intensity, muscle strength and PAD ($p > 0.05$) PAD had a significant association with disability, fear of injury, depression, and pain intensity ($p < 0.05$). H-PAL did not associate with any of the variables ($p = 0.43$) In the active group pre-LBP both PAD and PAL contributed significantly to the explanation of disability ($p < 0.05$).
Orrell et al (2007)	72 older patients (who had experienced a cardiac event) (mean age 73.2 years)	RT3 worn for 7 days. A day was defined as the period during which 70% of the population had recorded data and 80% of that observed period constituted a minimal day (11 hours)	To validate the "Health survey for England" PA questionnaire	Sensitivity and specificity of the HSE against the RT3 EE (in each of the 3 activity profiles) Low 0.35 (sensitivity), 0.92 (specificity) Medium 0.4 (sensitivity) and 0.56 (specificity) High 1.0 (sensitivity) and 0.76 (specificity)

Authors	Subject	RT3 and physical activity measures	Main purpose	Results
		Activity from RT3 expressed in kcals: Light = 2-5, Moderate > 5 and < 7.5 and vigorous > 7.5		Agreements (kappa) between RT3 and HSE (k = 0.08, p = 0.45) The HSE misclassified 63% of participants PA levels
Hertzog et al (2007)	65 patients (56 males and 9 females) aged between 64 and 86 recruited from hospitals prior to discharge after heart surgery	Participants wore an RT3 monitor for 3 days (including 1 weekend day) clipped to the waist-band at 3 weeks, 6 weeks and 3 months post-surgery. Activity diary	To estimate the number of days needed to reach adequate levels of reliability for measures of PA and EE obtained from a RT3 and daily activity diary at 3 stages of repeated measurement Secondary Aims: compare the estimates from the two methods at each stage and evaluate whether estimates of the amount of change over time were consistent between the two.	ICC values for the RT3ranged from 0.85-0.97 and diary values ranged from 0.76-0.94 (ICC of 0.8 and above was found in all RT3 3 day measurements) Correlations for daily calories (r = - 0.77-0.72-0.57, p < 0.05) Correlations of activity counts to calories/kg (r= 0.32-0.45-0.43, p < 0.05) Correlations of activity counts to mins of activity moderate or higher r = 0.24-0.43-0.46 (p < 0.05) (change r = 0.42) After removal of outliers correlations all improved significantly. The RT3 was consistently higher on EE over the 3 time periods. Mean differences were significant at 3 weeks and at 3 months (p < 0.05) but not 6 weeks (p = 0.41) Bland-Altman plots showed that RT3 estimates tended to be higher when the mean k/cals were below 2000.
Soundy et al (2007)	Fourteen (10 male and 4 female) attending a MIND (UK support charity) range of psychiatric illnesses	RT3 worn on the left or right hip for 7 days (5 days of RT3 data analysed. (expressed in VM/day) (a weekend and 3 weekdays) 7D-PAR	Main purpose to examine the validity and reliability of a 7D-PAR in individuals with severe mental illness	Correlation coefficient between RT3 VM/day and TEE (τ = 0.43, p <0.05); moderate (τ = 0.16, p = 0.23) and vigorous (τ = 0.08, p = 0.60) activities 7D-PAR overestimated moderate physical activity and TEE and underestimated vigorous

Authors	Subject	RT3 and physical activity measures	Main purpose	Results
				activities ($p < 0.05$). 7D-PAR test-retest reliability high (ICC = 0.97) A participant's mass and basal metabolic rate significantly affected the associations ($p < 0.05$)
Nguyen et al (2006)	8 subjects (5 men and 3 women) mean age 71 years.	Subjects wore the RT3 on the non-dominant side for 112 days. Biweekly assessments were made to assess symptoms and collect activity data. As well as telephone calls to improve adherence	To determine the feasibility of using an accelerometer to characterise PA patterns surrounding COPD exacerbations in patients with COPD for 16 weeks	
Klassen et al (2008)	36 subjects with MS completed data collection (including 9 active controls) (Mean age 46 years)	A TriTrac RT3 monitor worn on the waistband for 7 days (Total VM for 4 days recorded) The Human Activity Profile employed to recruit groups of low, moderate and high activity levels. 24 hour activity diary- (included categories of activity)	To examine the ability of two measures of PA to discriminate among groups of inactive, moderately active and active individuals with MS	The inactive and the moderately active groups had significantly lower scores than the active and control groups ($p < 0.05$). The diary showed a difference between the inactive and moderately active but no difference between the moderately active and active MS or controls ($p < 0.05$). Accelerometry and diary scores were significantly correlated ($r = 0.59$, $p < 0.05$) The Expanded Disability Status scale was significantly associated with accelerometry scores ($r = -0.64$, $p < 0.05$) but not with diary scores ($p = 0.15$)
Barnason et al (2008)	119 adults (aged > 65) dichotomised into fatigued and non-fatigued on the basis of self-	RT3 used to measure PA at 6weeks and 3 months after heart surgery.	To assess the relationship between fatigue and early postoperative	There was no difference in the mean RT3 kcals/kg/d between the two groups at either 6 weeks or 3 months ($p = 0.61$)

Authors	Subject	RT3 and physical activity measures	Main purpose	Results
	report of fatigue at 3 weeks post heart surgery	Self-report exercise diary	recovery outcomes over time in elderly patients undergoing coronary artery bypass surgery	No difference in RT3 scores between the two time points ($p = 0.43$)
Hale et al (2008)	17 men and 30 women (28-91) living in the community with stroke (20) Parkinson's (7) and MS (11) and healthy sedentary controls (9)	RT3- 6 units worn in centre of low back for 7 days TheRT3 mean VM for each day was reported- assessment of diary to look for discrepancies between diary and RT3 data Questionnaires included the RMI 7D-PAR and daily activity log and a specifically developed Utility questionnaire	To investigate the reliability, validity and utility of the RT3 to measure physical activity in free-living environment in adults with and without a neurological deficit	RT3 test re-test ICC 7-day values ranged from 0.68-0.85 and for 3-day (0.54-0.9) Group ICC 7day = 0.85 Group ICC 3day = 0.84 The absolute reliability (SE of measurement) was 23% T-tests showed a significant difference between 7 and 3 day data ($p < 0.05$). Bland Altman showed that the 3-day data could differ by 86,300 VM counts The mean RT3 VM had a low correlation with RMI ($r = 0.18$, $p < 0.07$) ROC analysis showed that the RT3 was more sensitive in distinguishing between people with varying degrees of mobility compared to the 7D-PAR ($p < 0.05$)
Sloane et al (2009)	154 Breast and prostate survivors (mean age 62 years)	RT3 worn for 7 days (returned by post) worn on the waistband of their pants – repeated at 1 year and 2 year follow-up RT3 outcome variable = total no of exercise minutes of moderate or higher intensity for one week	The primary aim was to evaluate the association between estimated weekly minutes of exercise from a self-report instrument (7D-PAR) and the RT3 A secondary objective was to evaluate the association between the 7D-PAR and the RT3 to	Three cross sectional correlations (baseline, 1 year and 2 year) showed significant correlations ($r = 0.54$-0.24) between RT3 and 7D-PAR ($p < 0.05$) 7D-PAR estimated an increase of 44.9min/wk in moderate and hard activities and the RT3 a decrease of 1.1 min/wk (Pearson correlation for the association of the change score = 0.11, $p > 0.05$) Overall the RT3 tended to overestimate hours

Authors	Subject	RT3 and physical activity measures	Main purpose	Results
			the sensitivity to change (difference from baseline to year 1 follow-up)	of moderate and hard activity ($p < 0.05$)
Hecht et al (2009)	Subjects were COPD patients on long-term oxygen use 22 subjects (14 men) were randomised (mean age 68 years)	RT3 – worn for 14 days on waist Asked to identify periods of non-wear and motor use (press flags on RT3 when entering a motor vehicle) Did not include data on the day of initiation or collection (excluded motor vehicle use data)	To develop a novel method to analyse accelerometry data that yields an accurate picture of PA To compose a computerised algorhythm to determine when the device was worn To allow construction of average activity profiles and calculation of the fraction of time spent at a specified activity	Subjects wore the activity monitor 11.4 (3) hours/day (47.5% time, or 75% of daily activity, range 5.8-19.7 hours/day Results showed that 7 days were required to assess the average RT3 VM counts/minute value to be within 10% of the 14 day average In 4 subjects (compliant) motor vehicle use = 51.2 minutes/day and removing these periods lowered average daily activity level from 84 to 70 VM counts/min
Garcia-Rio et al (2009)	110 patients with moderate to severe COPD (mean age 68 years)	RT3 worn for 5 days (1 minute epoch) RT3 output measured in VM counts/min 6-minute walk test and cycle ergo meter test	To analyse the contribution of dynamic hyperinflation, exercise tolerance and airway oxidative stress to PA in patients with COPD	Reduced PA was explained by dynamic hyperinflation and distance walked in the 6-minute walk test

BPAQ Baecke Physical Activity Questionnaire; PAL Physical activity level; PARS Physical activity recall survey; PAEE Physical activity energy expenditure; PAD Physical activity; RMI Rivermead Mobility Index; CHAMPS 42 item Community Healthy Activities Model Program for Seniors; PAD Perceived activity decline; PAL Physical activity in daily life; 7D-PAR Seven day recall questionnaire; COPD Chronic Obstructive Pulmonary Disease; HSE Health Survey for England

CHAPTER III

The relationship between LBP and physical activity: A Literature review

3 The relationship between low back pain and physical activity: A literature review

This review examines the role of activity in low back pain, and the research underpinning our knowledge in this area. The review begins with a brief overview of the epidemiology and prognosis of LBP as a full review of these fields is beyond the remit of this PhD. Outcome measures for LBP research are then reviewed and in particular specific measures of disability and function for prospective research in this field. Our current understanding of the role of activity in LBP is then reviewed in relation to its potential role in the onset, management, and prognosis of LBP. Specific objective measurement tools (focused on activity monitors) employed to monitor activity in LBP populations are evaluated, to allow a better understanding of the strength and limitations of our current knowledge in this field.

3.1 The relapsing remitting nature of low back pain

The epidemiology of LBP in primary care is poorly understood (Abbott and Mercer 2002); however it appears to be one of relapse and remissions (Majid and Truumees 2008). A review of LBP studies found that acute onset LBP decreased rapidly (by between 12%- 84%) within 1 month and continued to decrease (more slowly) until 3 months (Pengel, Herbert et al. 2003); however, only about one in three cases resolves completely over a 12-month period, with recurrence and relapse common (Majid and Truumees 2008). Disability decreased between 33-83% in the first month and between 68-86% returned to work over the same period (Pengel, Herbert et al. 2003). Other research supports the findings that acute LBP patients (i.e. a cohort with symptoms < 6 weeks' duration) (Grotle, Brox et al. 2004) make initial significant improvements in pain and disability (as a group) (Grotle, Brox et al. 2006; Gurcay, Bal et al. 2009); however variable changes in both pain and disability levels are reported in the literature at 3 months post episode, varying from 40% (Underwood 2004; Johnson, Jones et al. 2007) to 24% with persistent disabling LBP (Grotle, Brox et al. 2004). Overall, it is estimated that approximately three in five patients with an acute episode of LBP will recur in an on-going relapsing pattern, and about one in 10 do not resolve (Kent and Keating 2005).

3.2 Low Back Pain Outcome Measures

Research in LBP requires a defined set of outcomes measures to effectively evaluate the course of LBP and effects of interventions on LBP (Bombardier 2000). Two commonly used measures of back-specific function are recommended for prospective research: the Roland-Morris Disability Questionnaire (RMDQ) and the Oswestry Disability Index. Other outcome measure domains commonly employed in LBP research include pain and disability. The following review briefly examines the evidence for the RMDQ, the Visual Analogue Scale (VAS), and the Nordic Low Back Pain Questionnaire for prospective LBP research. These tools were chosen as they allow LBP outcomes to be evaluated over a 1-year period.

3.2.1 Roland Morris Disability Questionnaire

The RMDQ has been shown to be a valid measure of LBP disability, and a sensitive measure of change in functional disability in LBP populations (Turner, Fulton-Kehoe et al. 2003). This self-administered questionnaire consists of 24 items which refer to limitations of daily activities as a result of LBP. The RMDQ showed good reliability (ICC = 0.91) in a chronic LBP population (Brouwer, Kuijer et al. 2004), and demonstrated high one-week test-retest interval scores (ICC = 0.88) within a sub acute LBP group. The RMDQ has high construct validity when compared to other commonly employed measures of pain, disability, and patient quality of life within various LBP populations (Bayar, Bayar et al. 2003; Fujiwara, Kobayashi et al. 2003; Bayar, Bayar et al. 2004). The RMDQ is sensitive to change within acute (Grotle, Brox et al. 2004), sub acute, and chronic low back pain populations, with a moderate group effect size for both the improved group (-0.70 to -0.74) and deteriorated group seen (0.69 to 1.25) (Frost, Lamb et al. 2008) (Appendix page 237 - 239).

However, previous research has also found that the RMDQ lacks sufficient reliability and responsiveness as an outcome measure for clinical application (Davidson and Keating 2002). As such, a multi-level RMDQ has been developed, replacing the yes/no response option of the RMDQ, with hierarchical patient responses to improve the internal consistency, reliability, and construct validity (Chansirinukor, Maher et al. 2004). However, research suggests that assessment of the responsiveness of the RMDQ to change is dependent upon the outcome measure employed as the concurrent measure (Kuijer, Brouwer et al. 2005). Recent research found that patient variables including age, occupation, pain duration, and symptoms were significantly correlated with RMDQ ($p < 0.10$) in an acute LBP population (Schiphorst Preuper, Reneman et al. 2008). In multiple regression analysis, pain intensity ($b = 0.285$, $p = 0.004$), the SF-36 PCS ($b = -0.264$, $p = 0.001$), and depression ($b = 0.254$, $p = 0.008$) each

made a significant contribution to the prediction of RMDQ score (Wand, Chiffelle et al. 2010). These results suggest that the patient's psychological state is an important determinant of reported disability within an acute LBP population. Thus the RMDQ is a valid, reliable, and responsive method to assess disability and change in disability over time in both acute and chronic LBP populations. However, assessment of its psychometric properties through its relationship to other measures is dependant upon the population under study.

3.2.2 Visual Analogue Scale (VAS)

Measurement of pain is a common construct within prospective longitudinal LBP research, and considered a core predictor for baseline measurement within LBP populations (Pincus, Santos et al. 2008). The VAS pain measurement tool is used to measure the participant's level of pain over the past 7 days on a scaled measurement of pain (0 – 10). This tool has been shown to be a valid, reliable, and appropriate tool for use in clinical practice in populations with non-specific LBP (Williamson and Hoggart 2005), and is a sensitive measure of clinical change within LBP populations (Ostelo and de Vet 2005). The reliability of the VAS for disability in chronic pain is moderate to good (ICC = 0.76 to 0.84); however the measurement demonstrates only weak and variable correlations to other measures of disability in patients with chronic musculoskeletal pain (Boonstra, Schiphorst Preuper et al. 2008). However, a recent study found that self-reported disability and functional tests were significantly correlated to pain intensity ($r = 0.592$, $r = 0.457$, $p < 0.05$) (Wand, Chiffelle et al. 2010) in an acute LBP population, indicating that pain and disability are dependant upon the patient population, and that the VAS has reasonable construct validity within acute LBP populations (Appendix page 235).

3.2.3 Nordic low back pain questionnaire

The Nordic questionnaire has been used extensively as part of workplace ergonomic screening programs, and epidemiologic assessments of musculoskeletal disorders (Knibbe and Friele 1996; Kumar, Varghese et al. 1999; Descatha, Roquelaure et al. 2007). The questionnaire demonstrates good reliability and validity as a measurement and monitoring tool of musculoskeletal pain (Baron, Hales et al. 1996; Descatha, Roquelaure et al. 2007). The Nordic LBP Questionnaire has been previously employed as a measure of LBP recovery in an occupational setting (Hartvigsen, Bakketeig et al. 2001) and as a measure of LBP, for assessing the associations between PA and the incidence of LBP (Hartvigsen, Christensen et al. 2007), and to assess prognostic factors in occupational spinal disorders (Hagen, Magnus et

al. 1998). The Nordic questionnaire represents a valid instrument to assess musculoskeletal pain in the community (Appendix page 239).

3.3 Measurement of outcome domains in low back pain research

A range of potential outcome domains are recognised, and these are routinely assessed as part of studies in this area (Bombardier, 2000). The following briefly discusses measures of depression, anxiety, emotional distress, fear avoidance behaviours as recommended in LBP research. The Fear-Avoidance Beliefs Questionnaire (FABQ) and the 12-item General Health Questionnaire (GHQ12) are two such evaluative tools often employed in prospective LBP research.

3.3.1 Fear Avoidance Beliefs Questionnaire

The FABQ has been shown to be a reliable measure of pain-related fear in acute LBP populations (Swinkels-Meewisse, Roelofs et al. 2003), and demonstrates strong predictive validity for functional disability in both acute (Grotle, Brox et al. 2004) and chronic LBP populations (Woby, Watson et al. 2004). The questionnaire consists of two subscales: fear-avoidance beliefs about work (FAB-work), and fear-avoidance beliefs about PA (FAB-physical activity). Each question is arranged on a Likert scale from ‘completely disagree’ to ‘completely agree’ (0 – 6). The FAB-work consists of the points summed from items 6, 7,9,10,11,12 and 15 of the questionnaire (Appendix page 236), giving a maximum scale score of 42 (7 items). The FAB-physical activity consists of the points summed from items 2, 3, 4 and 5, giving a maximum score of 24 (4 items) and the higher the scale score, the greater the degree of fear and avoidance beliefs shown by the patient.

3.3.2 General Health Questionnaire

The GHQ12 is a validated measure of psychological distress in the general population (Bashir, Blizard et al. 1996) as well as in LBP populations (Croft, Papageorgiou et al. 1995). Prospective research has shown that GHQ12 scores predict future episodes of LBP (Feyer et al., 2000). Each of the 12 items is rated on a four-point scale (less than usual, no more than usual, rather more than usual, or much more than usual), and scored using the Likert system (0-1-2-3) giving a total score ranging from 0 to 36 (pages 242-243).

3.4 Prognostic Factors in LBP

An overview of various prognostic factors in LBP research is presented. A number of factors have been shown to be predictive of future disability and LBP recurrence. A recent study found that patients with lower than average initial pain intensity, shorter duration of symptoms, and fewer previous episodes, were 3.5 times more likely to be recovered at any time point (95% CI, 1.8–7.0) than patients without these characteristics (Hancock, Maher et al. 2009). These factors have also been identified as significant prognostic factors in other research (Bekkering, Hendriks et al. 2005; Enthoven, Skargren et al. 2006). However, psychological factors, including fear avoidance, depression, and self-efficacy have been found to be important factors in the prognosis of acute LBP (Grotle, Brox et al. 2005). However, discrepancies across prognostic LBP reviews in terms of differences in selection criteria and data interpretation potentially influence review conclusions. Therefore clinical and research guidelines for the management of and research on prognostic factors in LBP recognise the importance of both biomedical and bio-psychosocial factors and their interaction as predictors of LBP (Ferguson, Brownlee et al. 2008; Pincus, Santos et al. 2008). Most studies which have investigated prognostic factors in LBP have failed to include measurement of PA as a predictor variable. Therefore, the role of activity as a prognostic factor in either the incidence of LBP or its role in future chronicity and recurrence has not been fully evaluated. It is acknowledged that the measurement of activity in free living is problematic (Prince, Adamo et al. 2008), and this review begins by looking at the rationale for assessment and prescription of activity for LBP populations.

3.5 Models of deconditioning in LBP

The proposed effect of PA on LBP has to a large part been based upon the deconditioning model of LBP (Wittink, Hoskins Michel et al. 2000; Verbunt, Seelen et al. 2003), supported by evidence of various changes in physical functioning (Naliboff, Cohen et al. 1985; Brox, Storheim et al. 2005; Di Iorio, Abate et al. 2007), neuromuscular changes (Van Dieën, Selen et al. 2003; Hammill, Beazell et al. 2008), strength changes (Risch, Norvell et al. 1993), effects on pain levels (Geisser, Robinson et al. 1995), psychological effects (Storheim, Ivar Brox et al. 2005), decreases in physical fitness (Smeets, Wittink et al. 2006), and alterations in the patterns (van Weering, Vollenbroek-Hutten et al. 2009), and levels of activity of patients with LBP (van den Berg-Emons, Schasfoort et al. 2007).

The evidence for deconditioning as a result of LBP has been challenged (Smeets and Wittink 2007). Many studies demonstrate non-significant or equivocal relationships between activity levels and various measures of physical fitness (Nielens and Plaghki 2001; Smeets, Wittink et al. 2006), physical and lumbar movement parameters (Nourbakhsh, Moussavi et al. 2001; McCracken, Gross et al. 2002), and pain levels (Fordyce, Lansky et al. 1984; Vendrig and Lousberg 1997). Increasingly, studies have objectively measured fitness and activity parameters within LBP populations and compared these to age and gender matched "normals". However, a number of these studies report no difference in either fitness levels (Smeets and Wittink 2007; Rasmussen-Barr, Lundqvist et al. 2008) or activity levels of patients with LBP compared with healthy controls (Verbunt, Westerterp et al. 2001; Basler, Luckmann et al. 2008; Smeets, van Geel et al. 2009; van Weering, Vollenbroek-Hutten et al. 2009), and therefore the deconditioning models for LBP have been questioned. A recent review of the theoretical constructs underlying the deconditioning model for LBP reported the strength of evidence for such a model to be poor (Verbunt, Smeets et al. 2010). However, the majority of research in this field is cross-sectional, comparing physiological, morphological features and activity levels of patients with chronic LBP and matched healthy controls. Few studies have assessed these changes prospectively and specifically monitored activity levels with an objective measure to investigate potential relationships with outcomes over time. Thus, despite the lack of evidence for the deconditioning model, there is a need to prospectively evaluate potential relationships activity and LBP outcomes over time. The following section reviews the evidence for the role of activity in LBP management.

3.6 Physiological and behavioural adaptations to low back pain

Previous research which has investigated the effects of LBP on a range of physiological, behavioural, and psychosocial measures shows that the interactions are complex. Participants' behaviour can affect the interaction between measures of activity and LBP (Hasenbring, Marienfeld et al. 1994; Crombez, Vervaet et al. 1998; Brox, Storheim et al. 2005). Crombez et al 1998 investigated the behavioural coping strategies proposed for patients with LBP (Hasenbring et al 1994, Vlaeyen et al 1995) by assessing: the extent to which a LBP cohort avoided movement, or endured the movement until the pain forced them to stop; the amount of attention they paid to back pain; control of pain; fear of pain, and their fear of re-injury. Based upon responses to these questions they classified participants into avoiders and confronters of PA, whereby avoiders reported more frequent pain in activities and that the pain took longer to dissipate after the activity. Avoiders also reported a higher fear of pain,

and higher fear of re-injury and consequently more disability and more trouble with physical activities. A more recent study explored the factors that may contribute to deconditioning or loss of fitness in a chronic LBP population (Brox, Storheim et al. 2005). They found that fear avoidance behaviours were equally prevalent in both a sub-acute and chronic LBP population, suggesting that these factors appear at an early stage and may contribute to the transition from acute to chronic LBP. Fear avoidance beliefs for work, disability, and cardiovascular fitness were found to predict return to work over a one year period (Storheim, Ivar Brox et al. 2005). These results suggest a potential link between the fear of pain/(re)injury on one hand, and its effect on behaviour and consequently its potential to act as a mediator between PA and LBP outcomes (Burke, Beilin et al. 2008). Previous studies have demonstrated that behavioural factors can mediate the effects of PA on a range of health outcomes (Sallis, Calfas et al. 1999; Perruccio, Power et al. 2005; Molloy, Sniehotta et al. 2009). However, few studies have investigated behavioural factors (including fear avoidance) as potential moderating or mediating factors on the relationship between activity and LBP, and therefore this is an area to explore.

3.7 The role of bed rest and physical activity in acute low back pain

Activity prescription and advice to stay active, with an emphasis on early and gradual activation, and discouragement of bed rest, are current key features of primary care LBP management guidelines (Koes, van Tulder et al. 2001; Bekkering, Hendriks et al. 2003). Much of the evidence for these recommendations has arisen from research showing the benefits of activity as opposed to bed rest, considered standard treatment for acute LBP for much of the 19th century (Deyo, Diehl et al. 1986; Malmivaara, Hakkinen et al. 1995). Deyo et al 1986 was the first to challenge this assumption and investigated the effect of the number of days of bed rest in a group of patients with acute LBP randomised to differing lengths of bed rest . Results showed that two days of bed rest for patients with acute LBP had more favourable outcomes than seven days at both 3 weeks and 3 months post-episode. A further study challenged the accepted wisdom that a period of bed rest was necessary during a period of acute LBP (Malmivaara, Hakkinen et al. 1995). At both three and twelve weeks patients assigned to two days bed rest recovered more slowly than the control group who were advised to continue ordinary activities as tolerated. Interestingly, the results also indicated that recovery was slower in the group receiving specific back exercise compared with the controls at 12 weeks, suggesting that general activity advice may be more advantageous than targeted

back exercises for recovery. A number of reviews on the role of bed rest for acute LBP have since been conducted and updated over the past decade (Waddell, Feder et al. 1997; Hagen, Hilde et al. 2000; Hagen, Hilde et al. 2004; Hagen, Jamtvedt et al. 2005; Hagen, Hilde et al. 2007). The current consensus, based upon high quality review evidence, is that advice to rest in bed is less effective than advice to stay active for people during an acute episode of LBP. However, for patients with sciatica, there is little or no difference between advice to rest in bed and advice to stay active.

3.8 Guidelines for activity advice in low back pain

As a result of the wealth of evidence for the effectiveness of activity in LBP, there has been increasing emphasis on the role of exercise and PA for patients with both acute and chronic LBP (symptoms > 3months) as a prime strategy in international guidelines for the primary care management of LBP (Airaksinen et al., 2006b, Van Tulder et al., 2006a, Koes et al., 2001, Arnau et al., 2006). Evidence based guidelines, specifically for physiotherapists working in the primary care management of LBP, stress the avoidance of bed rest and advice to remain active for patients with both acute and chronic LBP (Maher, Latimer et al. 1999). A systematic review of 39 RCT trials involving 7347 patients assessed the effect of advice to remain active as a sole treatment or as an adjunct to treatment in various LBP populations (Liddle, Gracey et al. 2007). They reported that advice to remain active as an adjunct to exercise was most effective for improving LBP outcomes in patients with chronic LBP, and that simple advice to “remain active” was as effective as other included interventions for acute LBP. The results found a difference in the effects of advice for LBP dependent upon the phase and duration of the LBP episode. Only 15% (2/13) of all trials investigating advice for the management of acute LBP showed a positive result as compared to 86% (6/7) of those investigating sub-acute (symptoms present for 4 to 12 weeks, Van Tulder, Becker, et al. 2006) and 74% (14/19) of chronic LBP trials. The review also highlighted the wide discrepancies reported in activity advice given to patients at varying stages of their recovery in terms of both the types of advice, frequency and consistency of advice throughout the treatment. These results emphasise the potentially significant role that activity advice and information has in the management of both acute and chronic LBP. However, none of the included studies specifically investigated or measured the activity levels of participants within the trials to show if advice to remain activity changed activity levels, and/or if such changes were related to outcomes. The following section reviews the literature on studies which have specifically evaluated activity levels within LBP populations

3.9 Activity levels in low back pain populations

Activity levels have been investigated as an outcome measure in LBP populations using various recall questionnaires (Fordyce, Lansky et al. 1984; McCracken, Gross et al. 2002; Wormgoor, Indahl et al. 2006; Kuukkanen, Mälkiä et al. 2007), as well as objective measures of activity (Hasenbring, Plaas et al. 2006; McDonough, Liddle et al. 2008). Studies have assessed PA as an outcome measure in trials investigating the effectiveness of therapeutic interventions in both acute and chronic LBP populations (Cherkin, Deyo et al. 1996; McCracken, Gross et al. 2002; Damush, Weinberger et al. 2003; Basler, Bertalanffy et al. 2007). Studies generally demonstrate a significant and positive increase in the various dimensions of PA, irrespective of the primary intervention, both within and often between intervention groups. However, the changes in the levels and types of activity that occur over time appear to be complex in nature. Cherkin et al 1996 reported substantially higher levels of regular physical exercise in a group receiving education from a nurse in comparison to two other groups receiving usual medical care and an education booklet at 1 year. However, the actual levels of reported minutes of exercise per day were lowest in the nurse group and highest in the usual care group and overall the groups were the same in terms of the total amounts of regular physical exercise reported. Another study comparing the effects of the addition of counselling to physiotherapy treatment for chronic LBP patients found that average duration of PA, as measured by questionnaire, increased significantly in both intervention groups from pre- to post-treatment, but no further increase was seen at the 6 month point (Basler, Bertalanffy et al. 2007). Similarly, Leonhardt et al 2008 noted changes in the types of activities measured with the Freiburger Questionnaire on Physical Activity (FQPA) within a large population group (1378 patients) of which 60% were acute. The cohort was randomised into three intervention groups: guidelines on PA for acute LBP; guideline plus the addition of counselling; and a control group. Sports and leisure activities increased in all three groups (fairy uniformly) over the 6 month period and 1 year follow-up period, but changes in self-reported basic activities fell in all groups at 6 months and then returned to baseline levels at 1 year. In a long term follow-up of a LBP cohort it was found that of those who reported regular exercise at baseline, the majority (78% of women and 82% of men) reported regular exercise at the 5 year point (Mortimer, Pernold et al. 2006), suggesting that the vast majority of patients return and maintain their “normal” levels of activity after an episode of LBP.

Thus it appears that activity levels of patients with LBP increase during an intervention, irrespective of the type of intervention, but that changes are non-uniform in terms of the types

of activity change observed. Evidence also suggests that activity levels then “normalise” after the intervention, with the majority of studies finding no change in activity levels 3-6 months after the intervention. There are potentially a number of factors which may influence activity levels in free living and these are discussed in the following section.

3.10 Factors affecting activity levels in free living populations

A number of factors have been identified from the literature which affect activity levels within various population groups, including occupation, gender, age, ethnicity, socioeconomic and bio-psychosocial factors, as well as baseline activity levels and the presence of co-morbidities (Ransdell and Wells 1998; Cooper, Page et al. 2000; Troiano, Berrigan et al. 2008) A significant association was seen between college levels of activity and present activity levels (Sparling and Snow 2002), while Randell and Wells 1998 reported that race, income, ethnicity, and marital status were predictors of PA within a diverse sample of urban women. Another study found gender and age were the most important predictors of activity and inactivity within a large mixed cohort (Livingstone, Robson et al. 2001). Leisure time PA levels within middle aged males in France, the UK, and Ireland were also found to differ depending on the environment and differing socio-cultural factors between the countries (Wagner, Simon et al. 2003). Thus, potential predictors of PA are very much dependant upon the sample population under investigation, and potentially each of these factors may affect LBP outcomes (Pincus, Santos et al. 2008) and thus act as a confounder to the relationship between activity and LBP outcomes. Therefore consideration of these factors in the reporting of PA is important, particularly when assessing change in PA over time. Various factors have also been found to moderate and mediate the affects of PA on outcomes within other patient populations (Perruccio, Power et al. 2005; Motl, McAuley et al. 2009). Factors identified which negatively influence PA include levels of disability, depression, fatigue, and higher pain levels, while higher levels of social support and self-efficacy for managing the condition and for regular PA were found to positively moderate the relationship between activity and the health outcomes. The role of potential confounders in an acute LBP population will be discussed and reviewed in Chapter IV.

3.11 Relationship between activity levels prior to low back pain episode and LBP outcomes

A number of studies have explored the effect of activity levels prior to the onset of LBP and their influence and relationship with various LBP outcomes (Haldorsen, Indahl et al. 1998; Verbunt, Sieben et al. 2005; Enthoven, Skargren et al. 2006; Faber, Burdorf et al. 2006; Bousema, Verbunt et al. 2007). The majority of studies employed recall questionnaires to retrospectively collect activity levels of patients with LBP. One study found that active participation in sports had a positive association with quality of life and functional limitations at baseline and functional limitations at 6-months (Faber, Burdorf et al. 2006). However, a number of studies report no association between activity levels prior to the onset of LBP and outcomes, both cross-sectionally (Verbunt, Sieben et al. 2005) and over time (Bousema, Verbunt et al. 2007). In support of these findings, perceived fitness levels prior to onset of acute LBP within three occupational groups (nurses, heavy manual workers, and drivers) in New Zealand did not predict 3 month LBP outcomes, measured by ACC claim status (Fransen, Woodward et al. 2002). However, two studies found that high levels of exercise prior to the onset of LBP were a positive predictor of recovery and return to work (Haldorsen, Indahl et al. 1998; Enthoven, Skargren et al. 2006).

Low levels of PA reported prior to the onset of LBP were found to be a predictor of disabling LBP at one year, as measured by pain severity on day of visit (0-10) and the Hanover LBP activity schedule (Thomas, Silman et al. 1999). In prospective research employing an objective measure of PA (MTI uniaxial accelerometer) worn for 3-5 days within a childhood population, high PA levels reduced the odds of future low and mid back pain recorded over a three year period (Wedderkopp, Kjaer et al. 2009). A recent study of more than 8000 community dwelling adults investigated the relationship between activity levels and reports of LBP symptoms of greater than 3 months using the 1 year Short Questionnaire to Assess Health enhancing physical activity (SQUASH). Activities were classified into the following dimensions: daily routine activities (including commuter traffic, occupational and school-related physical activities, and domestic activities), leisure time activities, and sport activities. (Heneweer, Vanhees et al. 2009). A U-shaped relationship was found between activity levels prior to a LBP episode and reports of chronicity: both reports of sedentary behaviour and engaging in sports increased the odds ratio of chronic LBP, and these effects were more marked in females. Thus, levels and types activity prior to the onset of LBP have the potential to influence reports of disability and affect recovery. However, the heterogeneity of study

designs in terms of activity measurement, LBP populations, LBP outcomes employed, and measurement periods means that comparisons are difficult and therefore conclusions challenging to draw. The following briefly reviews the evidence for specific exercise in the treatment of LBP.

3.12 The role of exercise and activity programs in LBP management

There have been a number of reviews which have assessed the role of various forms of exercise in the management of LBP (Van Tulder, Malmivaara et al. 2000; Wessels, Van Tulder et al. 2006), generally showing a positive effect for exercise in improving disability and activity limitation, particularly for patients with chronic LBP. Review evidence also highlights heterogeneity in study designs, including differing combinations of exercise, outcome measures, and levels of exercise, which make it difficult to draw definitive conclusions on the specific effectiveness of exercise for the treatment of either acute or chronic LBP (Bell and Burnett 2009). However, recent review evidence suggests that specific sub-grouping and targeting of exercise (Kent, Mjøsund et al. 2010) and supervised exercise programs potentially have the greatest efficacy in the management of non-specific LBP (Henchoz and So 2008). However, none of these exercise programs specifically targeted patient activities, and the next section reviews the evidence for the use of activity programs in the management of LBP.

Graded activity programs, often based on cognitive behavioural principles, have been trialled as a management strategy for acute and chronic LBP populations (Lindstrom, Ohlund et al. 1992; Staal, Hlobil et al. 2004; Hlobil, Staal et al. 2005; Steenstra, Anema et al. 2006). These programs do not specifically focus on PA, but rather a graduated exercise protocol of increasing intensity and load. Current evidence shows that advice to return to modified work and graded activity programs are effective in reducing work absenteeism (Loisel, Buchbinder et al. 2005); however included studies in this review did not measure activity levels in free living, and thus it is not possible to determine the inter-relationships between PA levels and activity programs and LBP recovery.

3.13 Role of activity in occupational LBP

Occupational LBP is defined as LBP directly attributable to work related activities (Oleske, Lavender et al. 2006). The role of activity level as a predictor for return to work in patients with acute LBP has not been established (Steenstra, Verbeek et al. 2005); however none of the included studies objectively and prospectively measured PA, and its relationship to outcomes. Also, few studies have specifically included PA within the prognostic model for occupational LBP. Therefore, currently there is limited evidence for the role of PA in the prognosis of occupational LBP (Haldorsen, Indahl et al. 1998; Storheim, Ivar Brox et al. 2005; Oleske, Lavender et al. 2006). One study found that regular exercise outside of work (Y/N) tended to protect against recurrence of work-related LBP (Oleske, Lavender et al. 2006), and another reported that leisure time PA levels were predictive of return to work in patients who had undergone a light mobilisation program after initial LBP sick leave (Haldorsen, Indahl et al. 1998). Storheim et al 2005 also found a significant positive relationship between higher fitness levels and return to work in patients with chronic LBP. However, none of these studies objectively measured activity levels of patients with LBP to investigate the potential inter-relationships with the outcome measures. The following reviews the evidence for objectively captured activity within LBP populations.

3.14 Measurement of activity in LBP populations employing activity monitors

A number of different types of activity monitor have been employed in various LBP populations to measure and quantify activity, and for various different purposes including measurement of PA as an outcome measure (Vlaeyen, de Jong et al. 2002; De Jong, Vlaeyen et al. 2005; McDonough, Liddle et al. 2008); to investigate differences in activity levels between populations with LBP and healthy controls (Verbunt, Westerterp et al. 2001; Spenkelink, Hutten et al. 2002; van den Berg-Emons, Schasfoort et al. 2007; Ryan, Grant et al. 2009; van Weering, Vollenbroek-Hutten et al. 2009); to assess sleep and awake times as well as mobility during sleep (Liszka-Hackzell and Martin 2005); to assess validity of activity monitors within LBP populations (Bussmann, van de Laar et al. 1998; Verbunt, Westerterp et al. 2001; Liszka-Hackzell and Martin 2002; Ryan, Gray et al. 2008); and to investigate interactions between various health outcomes and LBP outcomes activity (Verbunt, Sieben et al. 2005; Bousema, Verbunt et al. 2007; Ryan, Gray et al. 2010) (Table 3-1).

3.14.1 Use of activity monitors as outcome measures in low back pain populations

Two studies investigated the effects on PA of various interventions in a small sample of patients with chronic LBP (Vlaeyen, de Jong et al. 2002, De Jong, Vlaeyen et al. 2005). Six chronic patients were randomised to receive a set of individually tailored and ordered physical movements followed by graded activity. In the second intervention, the sequence of treatment modules was reversed (Vlaeyen, de Jong et al. 2002). In a similar design, six patients with CLBP were randomised to receive a single educational session, followed by a no-treatment period. Patients were then randomly assigned to either a graded exposure with behavioural experiments or an operant graded activity program (De Jong, Vlaeyen et al. 2005). Both studies employed a uniaxial accelerometer which was worn by participants for 1 week attached to a waist mounted belt, following each intervention within the study. Activity was calculated by summation of activity counts and then divided by the total time the monitor was worn. In both studies PA significantly increased following the interventions and there was also a noted decrease in pain related fear, which corresponded with a decrease in pain disability and pain vigilance, and an increase in PA levels (Vlaeyen, de Jong et al. 2002), thus demonstrating a potential relationship between both pain and fear avoidance behaviours and PA.

A methodological outline for a randomised control trial (RCT) details the use of an ActivPal to measure activity in a repeated measures design within a population with chronic LBP (McDonough, Liddle et al. 2008). The ActivPal is a uniaxial accelerometer which is attached to the anterior thigh and collects data on the amount of time the participants spend in upright, waking, and sitting and lying activities (Ryan, Gray et al. 2008). However, none of these studies have assessed the relationship between measured activity and LBP outcome measures. The following examines the evidence for a relationship between objective measures of activity and LBP outcome measures.

3.14.2 Assessment of physical activity with an activity monitor to investigate the relationship to low back pain outcomes

Relevant studies are summarised in Table 3-1. Only one study has employed an objective measure of activity in a prospective design to assess the relationship between PA and LBP outcomes in an adult population (Bousema, Verbunt et al. 2007). A triaxial accelerometer (RT3) was worn on two separate occasions for 7 days 1 year apart within a population with sub-acute LBP. The study found no difference in activity levels (RT3 VM counts/day),

calculated by subtracting the activity counts at 1 year from the counts at baseline, in those patients who had recovered versus those who had deemed non-recovered at one year, based upon their Quebec Back Pain Disability Scale (QBPDS). Activity change was not found to be a predictor of disability within this cohort; however both depression and the patient's perceived activity decline were predictive of activity change measured with the RT3. The authors also reported utility issues in that 16% of patients at follow-up at 1 year had invalid data due to RT3 malfunction or recording less than 5 days of data.

A number of cross sectional study designs have been employed to investigate the relationship between activity, measured with an activity monitor and LBP outcomes within various LBP populations (Busser, De Korte et al. 1998; Verbunt, Sieben et al. 2005; Hasenbring, Plaas et al. 2006; Ryan, Gray et al.). Activity measurement periods have ranged from 8 hours (Hasenbring, Plaas et al. 2006) to 7 days (Verbunt, Sieben et al. 2005). Furthermore, various types of activity measures have been investigated including differentiation of the patient's daily activities into standing, walking, and lying (Busser, De Korte et al. 1998; Hasenbring, Plaas et al. 2006). In contrast, another study used the RT3 VM counts/day accumulated as the measure of the patient's activity level (Verbunt, Sieben et al. 2005). Few utility problems have been detailed with the activity measurement, with only one study reporting an issue whereby 12 patients had less than 5 days of RT3 measurement (based upon insufficient battery charge) (Verbunt, Sieben et al. 2005). A range of outcome measures were used (Table 3-1) including pain, disability, and bio-psychosocial measures. Overall, the studies reported no relationship between the various measures of activity and measures of pain and disability; however, Ryan et al. 2010 reported that levels of activity were significantly lower in the distressed group of patients with chronic LBP compared to the non-distressed group. Thus, this review found little prospective research investigating the relationship between objective PA measurement and LBP outcomes. Evidence from cross-sectional studies indicates that there is little association between activity and LBP outcomes, and any potential relationship between PA and LBP outcomes may be mediated by psychological factors such as depression.

Table 3-1 Studies measuring activity with an activity monitor in free living LBP populations

Authors	Participants and Selection	Methods	Activity Measures, Measurement of LBP and Outcome Measures	Main Findings
Hasenbring (2005)	24 patients post lumbar disc surgery (5-9 months) Selection process 24-60 (9 men, 15 women)	Participants wore the triaxial accelerometer for at least 8 hours during one normal weekday All 24 participants wore the accelerometer for 8 hours Divided into two classifications based upon responses to the various questionnaires. Adaptive copers (AC) and Endurance copers (EC)	Triaxial Accelerometry (consisting of two sensors) worn at the waist and on lower leg Data classified into; Locomotion; Standing Sitting and Lying; Forward standing and sitting PAL expressed as total sum of counts in 8 hour period and separated into Constant Postures (CP) or Dynamic Postures (DP) Average Pain Intensity during the preceding week Average and maximal pain intensity in previous 3 months (using self-rating numerical scale). Self reported physical functioning using Physical functioning scale. Fatigue: MFI Pain Related Thought Suppression and Endurance; TSS, BES, KPI. Pain Related anxiety and avoidance behaviour The ADS of the KPI	Accelerometry data did not show a significant relationship with pain ($r = 0.03$, $p < 0.05$) Both groups (pain group and non pain group) showed no difference in accelerometry data ($p > 0.05$) Patients grouped as: N= 9 (AC); N = 14 (EC); 1 = Fear avoidance coping No difference in PAL between both groups. EC did have a significantly higher level of constant postures ($p < 0.05$)
Van Weering et al (2008)	29 Patients with non-specific LBP 918-65) with no co morbidities and 20 controls Mean age 44 (55% men)	Participants wore the accelerometer for 7 consecutive days (pre-rehab program)	A MT9 inertial 3-D motion sensor was used in combination with a MOB18-MT9 data logger RMDQ, pain complaints, work status, physical load Activity diary- to define work and leisure days	No difference between days (controls and CLBP) in mean acceleration/minute ($p < 0.05$) Activity levels of patients in the morning at weekends was significantly higher and lower in the evenings ($p > 0.05$)

Authors	Participants and Selection	Methods	Activity Measures, Measurement of LBP and Outcome Measures	Main Findings
				Patient group activity levels did not differ significantly at the w/e ($p > 0.05$) Activity patterns differed between patients and controls ($p < 0.05$) but no difference in overall activity levels between group ($p = 0.34$)
Van den Berg-Emons (2007)	18 subjects (4 men, 14 women) with chronic pain who participated in a rehab programme Age and gender matched controls	Cross-sectional measurement of activity levels comparing CLBP to controls over 1 day Assessed duration of walking, number of transitions, and mean mobility between groups	AM- Temec Instruments BV (consists of 4 accelerometers) – able to differentiate lying, sitting, standing and walking activities One accelerometer attached to each thigh and two to the sternum Data recorder attached (around waist) Measurement was performed for 1 weekday	Mean mobility was significantly lower (19%) in patients than controls, ($p < 0.05$) Differences in duration of dynamic activities were not different between neck, back and other chronic pain areas ($p > 0.05$). Patients spent considerably less time sitting and more time lying than controls ($p < 0.05$)
Verbunt et al (2001)	13 patients (9 men, 4 women) mean age 45 with non-specific CLBP. Referred by the Dept of orthopaedics, rheumatology and rehab) or participated in previous study. Age and gender matched controls	Compared activity levels in patients and controls Measured RMR, percentage of body fat and residual lung volume Measured BMI; ADMR measured using doubled labelled water PAL = ADMR ratio to RMR	Triaxial accelerometry attached to lower back collected for 14 days uninterrupted Tampa Scale for Kinesiophobia (TSK), VAS	No difference in ADMR in healthy controls and CLBP patients ($p < 0.05$) Correlation between accelerometry and DLW in CLBP was $r = 0.72$; ($p < 0.05$) and $r = 0.63$ (when expressed as ADMR-RMR) The RMDQ, TSK and VAS showed no correlation with DLW or accelerometry data ($p > 0.05$)
Liszka-Hackzell and Martin (2004).	15 acute LBP (<2 weeks duration) aged between 18-75 CLBP >6 months duration	Compared activity levels and pain in acute LBP and CLBP patients Use of an electronic diary (prompts) every 90 minutes to record pain Cross Correlation of Pain diary	Accelerometer- ActiWatch- sampling epoch 1 minute (All participants were required to completes at least 14 complete time series to be included in the study)	Significant decrease in pain levels in acute LBP over the 3 week time frame ($p < 0.05$) The pain levels of the CLBP group remained unchanged ($p = 0.61$) Cross correlation in activity and pain was strongest during the first week in ALBP ($p <$

Authors	Participants and Selection	Methods	Activity Measures, Measurement of LBP and Outcome Measures	Main Findings
		and activity levels Each patient monitored pain and activity levels for 3 weeks using ActiWatch.		0.05). There was no correlation in the CLBP group ($p > 0.05$).
Spenkelink et al (2002)	CLBP patients on a waiting list for multi-disciplinary treatment. Age 20-55, with > 6 months duration 10 Healthy controls	Measured activity for a 24 hour period. Ten controls and 6 patients were measured for 5 consecutive days In addition- asked participants to complete a checklist- asking about factors that might influence activity levels including alcohol or drugs. Looked at analysis of activity patterns in night, day and evening separately	Dynaport ADL monitor (provides info on static and dynamic tasks) 1 accelerometer worn on the left leg and 2 on the right. Worn for 24 hours Quebec Back Pain Disability Scale Overall levels of PAL from combining static and dynamic activity, walking step frequency and trunk movement.	Main results – an overall lowering of PA levels (esp. in the evening) in CLBP patients ($p < 0.05$) A large but similar day to day variability in activity patterns in the two groups ($p > 0.05$)
Liszka-Hackzell and Martin (2005).	18 patients diagnosed with CLBP	Pain diary, (0-10) every 90 minutes. Recorded sleep parameters and pain levels for 6 consecutive days.	Night time activity recorded using an Actigraph (sleep software package) worn on non-dominant arm Used a Self Organizing Map (SOM) to analyze the data	Found no correlation between daytime pain levels and sleep the previous night ($p < 0.05$). Correlation of PA at night and daytime pain ($r = 0.30$, $p < 0.05$)
Wedderkopp et al (2003)	806 participants (254 female, 227 male children and 165 female and 160 male adolescents 410 children and 295 adolescents wore CSA accelerometer	To assess the associations and dose response connections between back pain (including mid back) and self reported PA levels in the previous month. Accelerometry employed to validate the associations with the outcome variables.	CSA accelerometer worn for 4 days.	No association found between PA levels (from both questionnaire data and CSA data) ($p < 0.05$) and self-report of back pain in the previous month. There was a significant association with overall level of self-report and objective measures of PA ($p < 0.05$). Correlation was 0.25 and adjusted $R^2 = 0.14$ ($p > 0.05$). There was no statistically significant association

Authors	Participants and Selection	Methods	Activity Measures, Measurement of LBP and Outcome Measures	Main Findings
		Information on activity and inactivity was collected through a computer aided questionnaire.		between physical inactivity and objective measures ($p > 0.05$).
Bussmann et al (1998)	10 participants with failed back surgery.	To investigate the validity of an activity monitor in a population with failed back surgery. Each of the participants performed a number of ADL's (from a list of 32) around their own home Statistical analysis to assess the agreement, sensitivity and predictive value of the accelerometery data vs. the video recording	Four uni-axial accelerometers (one on each thigh and two on the sternum) - Video recording The AM is able to distinguish static from dynamic activities. Tampa scale for Kinesiophobia (TSK) RMDQ	Overall results show an agreement between activity output and video analysis of 87%.
Bousema et al (2007)	124 Patient with sub-acute low back pain (4-7 weeks) Screening performed to check for inclusion- (Fass et al 1996)	Longitudinal cohort study to evaluate the development of disuse in patients with back pain during 1 year after pain onset. Predictors for change in PA were assessed with multiple logistic regression	PAL measured with the RT3- worn for 7 days. Assessed twice at inclusion and 1 year. The change in PA was expressed as T1-T0 The perceived level of PA decline (PAD) using the modified Physical Activity rating Scale and the Baecke Physical Activity Questionnaire and the level of PA in the 1 year prior to pain. Levels of physical fitness: BW, percentage body fat and muscle strength of quads. PCS TSK	Recovered patients shoed an increase in activity of 12.9% ($p > 0.05$) No difference in the PAL changes between groups (recovered to non- recovered) ($p > 0.05$) Depression and PAD had a small but significant predictive value for PAL change ($p < 0.05$).

Authors	Participants and Selection	Methods	Activity Measures, Measurement of LBP and Outcome Measures	Main Findings
			Quebec Back Pain Disability Scale (QBPDS) Beck Depression Inventory (BDI)	
Verbunt et al (2005)	123 patients (66 male and 57 female) with 4-7 weeks of non-specific low back pain Mean age of 44.1 years (SD = 10.3)	Cross sectional measurement of physical activity for 7 days Physical activity in daily life after the onset of pain (PAL) used an RT3 (1 minute counts/minute). Output in counts/minute also used an activity diary.	Physical activity in daily life before the onset of pain (H-PAL) measured with the BPAQ Physical Activity = total sum of counts/day RT3 worn for 7 days Perceived Physical Activity Decline 20 different activities were derived from the PARS and patients were asked to indicate how often in the last 2 weeks they had performed the activity. Muscle strength VAS score QBPDS TSK	No association between PAL and disability, fear of injury, depression, and pain intensity, muscle strength and PAD ($p > 0.05$). A significant association between disability and H-PAL ($p < 0.05$) PAD had a significant association with disability, fear of injury, depression, and pain intensity ($p < 0.05$). No difference in the PAL levels between those with low and high H-PAL ($p > 0.05$) In the active group pre-LBP both PAD and PAL contributed significantly to the explanation of disability ($p < 0.05$).
Vlaeyen et al (2002)	A replicated single –case design. Included 6 consecutive patients with CLBP referred for outpatient behavioural rehabilitation (included participants with surgery)	Participants underwent one of 2 interventions exposure in vivo first (EXP) followed by graded Activity (GA).In the 2nd the sequence was reversed. Baseline period (A) for 4 weeks, then period B (4 weeks) and C (4 weeks)	Patients wore a uniaxial monitor attached to the belt for 1 week and a diary of activities Movement counts were added and divided by the time carried (carried X 3) in A, B, and C groups. TSK, SCL-90 and the PHODA (a hierarchy of fear eliciting movements	Increase in activity observed after intervention and not after GA. After intervention, the increase in movement counts compared with baseline equals a z-score of 7 SDs (no p value) Decreases in pain related fear concurred with decreases in pain disability and pain vigilance and an increase in PA levels (no p values)

Authors	Participants and Selection	Methods	Activity Measures, Measurement of LBP and Outcome Measures	Main Findings
		The intervention period is patient education and behavioural tests to assess fear of pain and movement	Pain vigilance and awareness (PVAQ). VAS RMDQ	
Busser et al 1998	1 patient with CLBP	Main locomotion activities were denoted for each day (locomotion, standing, sitting and lying) On day 1 he performed a maintenance job and day 2 a messenger job. The participant was filmed during the activities. One monitor worn on a belt around the waist and a 2nd around the thigh to discriminate activities of daily living	Patient wore the Dynaport on 2 separate days Activity was calculated and expressed as 0-6. 0- lying quietly 3= walking at a moderate pace and 6= high end activity = jogging Every 30mins the patient rated his pain on a VAS	Pain was related to activity and reductions of LBP were achieved by variation of periods of standing and walking with sitting. Causative factors for an increase in LBP appeared to be a lack of variability in activity and static loading Relationships between pain and PA
De Jong et al 2005	6 patients with LBP and high levels of fear avoidance (TSK) with non-specific LBP > 6 months (aged 18-65)	Patients randomly assigned to either education, behavioural experimentation or graded activity program.	Dutch version of TSK Pain Vigilance and Awareness Questionnaire RMDQ Patients wore an activity monitor close to the spine (uniaxial) for 1 week Movement counts were divided by the total time the monitor was worn. The activity monitor was worn four times	Mean standardised activity scores only improved with behavioural experiments ($p < 0.05$) However both groups showed a decrease in disability levels (significant in RMDQ) ($p < 0.05$)

Authors	Participants and Selection	Methods	Activity Measures, Measurement of LBP and Outcome Measures	Main Findings
Ryan et al 2008	Ten participants with CLBP (9 female and 1 male)	To investigate the validly of the ActivPal^{TM} to measure PA in a group of patients with CLBP. The output from the monitor was used to classify postural activities into lying, sitting or standing. A physiotherapist using a video camera analysis system verified whether the patient was lying, sitting, standing or walking Patients were asked to perform set tasks from a list in the lab and lie, sit, stand and walk on the treadmill (randomised) – each task lasted 3-6 minutes.	RMDQ VAS BMI ActivPal^{TM} worn on the anterior thigh for 7 days	Overall agreement between the monitor and observation was 97% with sensitivity and PPV ranging from 92-99%. The 95% limits of agreement for step counts was very high (<1%)
Ryan et al 2009	15 CLBP recruited from PT outpatients (18-65) – 15 healthy controls matched for gender, age and occupation	Measured PA in people with CLBP and healthy matched controls	Activity monitor ActivPal^{TM} worn for 24 hours/day for 7 days (front thigh) Activity measured as time in standing, walking and steps (separated into work days and non-work days) Pattern of PA measured as number of steps and cadence during short (< 20 steps), moderate (20-100) and long (>1000 RMDQ Pain diary	CLBP group spent 0.7 fewer hours walking and took 3480 fewer steps than controls (no difference in standing) ($p < 0.05$) CLBP also spent less time walking in the evening than healthy controls (in general on a non-work day they did the same number of steps as the healthy controls) ($p < 0.05$) CLBP group took fewer steps during both moderate and longer walks than healthy controls) ($p < 0.05$)

Authors	Participants and Selection	Methods	Activity Measures, Measurement of LBP and Outcome Measures	Main Findings
Chastin and Granat 2009	Healthy group with an active occupation (n = 54), a healthy group with a sedentary occupation (n = 53) and a group of subjects with CLBP (n = 5) and chronic fatigue (n=14)	Cross-sectional study measurement with the ActivPal for 3-7 days Sleep time and sitting time, sedentary behaviour Measured the amount of sedentary time, distribution of the length of sedentary bouts	ActivPal worn for 3-7 days	Subjects spent approx 75% of their time in sedentary behaviour Occupation and/or disease did not affect total sedentary time but it did affect the patterns ($p < 0.05$) Sedentary periods of those with chronic disease and sedentary occupations were accumulated in longer periods
Liszka-Hackzell and Martin (2002).	15 patients with acute low back pain (<6 months) 25 patients with chronic low back. Age 18–75	Activity measurement consisted of two components; a stochastic component reflecting random activities and a deterministic component corresponding to the general trend of activity.	Activity levels were monitored using an AW-64 Actiwatch (Mini-Mitter Inc.). Patients were asked to wear it continuously on their non dominant arm for 3 weeks Data collected between 0800 and 2200 each. Any patient who had not collected at least 14 complete time series (14 days) was excluded McGill Pain Questionnaire (MPQ2) SF-36 questionnaire (SF-36-1) Electronic Symptom Diary	Separation of activity measurements was done using threshold filtering. Good correlation between the true and predicted values for general health ($r = 0:96$, $p < 0:01$) and mental health ($r = 0:80$, $p < 0:01$).

ADMR Average daily metabolic rate; CPG; Chronic Pain Grade CPG; MFI The multi-dimensional fatigue inventory; PAL Physical activity level; TSS The Thought Suppression Scale; BES Behavioural Endurance Scale KPI Kiel Pain Inventory; ADS The anxiety depression scale; VAS Visual Analogue Scale: RMDQ Roland Morris Disability Questionnaire: DLW Doubly labelled water: CLBP chronic low back; QBPDS Quebec Back Pain Disability Scale; PAD Physical activity decline; PARS Physical Activity Rating Scale; PCS Pain Catastrophising Scale; TSK Tampa Scale for Kinesiophobia; RMR Resting Metabolic Rate; BDI Beck Depression Inventory; ODI Oswestry disability index: FABQ Fear avoidance beliefs questionnaire; FABQ Fear Avoidance Beliefs Questionnaire: IPAQ International Physical Activity Questionnaire: AC: Adaptive copers EC: Endurance copers; TSK: Tampa Scale for Kinesiophobia; PPV: Positive Predictive Value

3.14.3 Comparison of activity between populations with low back pain and healthy controls with an activity monitor

Studies which have assessed and compared activity levels in LBP and non-LBP populations have all employed a cross-sectional design, and exclusively within populations with chronic LBP. The activity monitoring period ranged from one day (Spenkelink, Hutten et al. 2002) to 7 days (Verbunt, Westerterp et al. 2001; Ryan, Grant et al. 2009), with a variety of activity measurement tools used. Van Weering et al. 2009 employed a 3-D motion tracker for 7 days and calculated activity as the mean counts/minute over the 7 days of monitoring. Other studies used activity monitors which differentiated activities of daily living including the Dynaport ADL monitor (Spenkelink, Hutten et al. 2002), and the AM-Temec Instrument BV (van den Berg-Emons, Schasfoort et al. 2007). These instruments provided information and quantification on standing, walking, lying, and stepping activities of the patient. Two studies employed the ActivPal (Ryan, Grant et al. 2009; Chastin and Granat 2010) which is worn continuously by attachment to the anterior thigh, and provides information on the relative frequency and time spent in standing, walking, steps taken, and lying time. Activity patterns across the day were also assessed and analysed in two further studies (Spenkelink, Hutten et al. 2002; van Weering, Vollenbroek-Hutten et al. 2009) as well as activity patterns, step numbers, and cadence within work days and non-work days (Ryan, Grant et al. 2009).

Three studies reported an overall lowering of various measurements and dimensions of activity in chronic LBP populations compared with control populations (Spenkelink, Hutten et al. 2002; van den Berg-Emons, Schasfoort et al. 2007; Ryan, Grant et al. 2009). One study found no difference in the overall levels of activity over a 7 day monitoring period between a chronic LBP population and healthy controls. However, they did report differences in the daily patterns of activity between the two groups, with patients showing significantly higher activity levels in the morning ($p < 0.001$) and significantly lower activity levels in the evening ($p < 0.01$), compared to a matched control group (van Weering, Vollenbroek-Hutten et al. 2009). Thus, there is mixed evidence that activity levels differ between patients with CLBP and matched controls; however, such variations are potentially due to differences in the patient populations investigated, number of patients and controls recruited, differences in the activity monitors employed, and activity measurement and analysis used.

3.14.4 Validity of activity measurement with an activity monitor in low back pain populations

A number of studies have investigated various components of validity for activity monitors to measure activity within adult LBP populations (Bussmann, van de Laar et al. 1998; Verbunt, Westerterp et al. 2001; Liszka-Hackzell and Martin 2002; Ryan, Gray et al. 2008). Bussmann et al. 1998 reported high correlations and associations between the accelerometry activity data and short-term observational video analysis in a laboratory setting. Also, moderate correlations were reported between Tritrac activity counts and DLW collected over 14 days in a population with chronic LBP ($r = 0.72$, $p < 0.05$) (Verbunt, Westerterp et al. 2001). One study assessed activity levels with a wrist worn uniaxial accelerometer and reported good correlation between the activity data and general health ($r = 0.96$, $p < 0.01$) and with mental health ($r = 0.80$, $p < 0.01$) in a chronic LBP population (Liszka-Hackzell and Martin 2002). In contrast, Ryan et al. 2008 found only low to moderate correlations ($r = 0.32$ to 0.44, $p < 0.05$) between data collected from the ActivPal in a lab setting and three functional task measures. These results suggest that activity monitoring is a valid method for assessing PA in free living within various LBP populations; however construct validity is dependant upon the population under study, the measurement tool, the dimensions of activity measured, and the duration of activity measurement. These data also highlight the need for further research to validate activity monitors within LBP populations

3.15 Summary of objective activity measurement methods in low back pain populations

A range of activity measurement periods have been employed, including short-term cross-sectional field research (Spenkelink, Hutten et al. 2002; Hasenbring, Plaas et al. 2006; van den Berg-Emons, Schasfoort et al. 2007; Ryan, Gray et al.), lab based or structured assessment of activity (Busser, De Korte et al. 1998; Bussmann, van de Laar et al. 1998; Ryan, Grant et al. 2008), and prospective research in the field. A range of activity monitors were employed, including both uniaxial and triaxial accelerometers and a range of measurement periods (1 day to 14 days) used. However, there was no consistency in reported period of measurement or definitions of a ‘day’ of recorded activity across the reviewed studies. In some studies there was no report of the amount of hours of activity data required to be classified as a complete ‘day’ of activity measurement, and/or a record of the amount of hours of activity data collected (Verbunt, Westerterp et al. 2001; Vlaeyen, de Jong et al. 2002;

Verbunt, Sieben et al. 2005). In one study participants were instructed to wear the monitor for four days, and data from those who wore it for a minimum of 3 days for 10 hours a day were included in the analyses (Wedderkopp, Leboeuf-Yde et al. 2003), while another reported that 5 of the 7 days of RT3 accelerometry data had to be available, including a weekend day, to be included in the analyses (Bousema, Verbunt et al. 2007). A further study collected data between 8 am and 10 pm each day, and required at least 14 complete days of activity data to be included (Liszka-Hackzell and Martin 2002). Thus, reporting of activity measurement has been inconsistent, and the recording period for activity measurement has varied across the reviewed studies.

Various methods have been utilised to calculate and analyse activity data, including separation into standing, walking, and step numbers, as well average and total accelerometer activity counts from the measurement period. Additionally, variability in activity was explored both across weekdays and weekend days (Busser, De Korte et al. 1998; Spenkelink, Hutten et al. 2002). A number of studies also used an activity diary to cross-validate the data collected from activity monitors (Vlaeyen, de Jong et al. 2002; Verbunt, Sieben et al. 2005; van Weering, Vollenbroek-Hutten et al. 2009). These results reflect that there is no "gold-standard" measurement for free living activity, and thus activity measurements vary depending upon the focus of the activity construct and dimension in the population under investigation.

Studies used both waist and wrist worn monitors, which the participants removed and re-affixed; a number of associated technical and compliance issues were reported (Verbunt, Sieben et al. 2005; Bousema, Verbunt et al. 2007; van Weering, Vollenbroek-Hutten et al. 2009). One study reported utility issues with the RT3 which included monitor and battery failure (Bousema, Verbunt et al. 2007). However, studies in which the activity monitor was affixed to the patient and was thus worn 24 hours/day, did not report on any specific utility issues with the monitors (Ryan, Gray et al. 2008; Ryan, Gray et al. 2009). Thus, utility issues are rarely reported in studies which have employed activity monitors in LBP populations, and these appear to be dependant upon the type of activity monitor that is used.

Overall, studies employed variable approaches to measure and classify PA within LBP populations. Results suggest that the monitors are potentially valid to use as measures of free living activity within this population. However, few studies have evaluated the relationship between activity and LBP outcomes in free living in a prospective design. The following

section briefly reviews the literature on LBP outcome measures employed for prospective research.

3.16 Overall Summary

There is a need to evaluate cost-effective methods to manage LBP within the community (van der Roer, Goossens et al. 2005), and to provide objective evidence for the role of activity in the management of LBP (Krismer, van Tulder et al. 2007). This review found that at present although activity advice remains a mainstay within international guidelines for the management of LBP (Arnau, Vallano et al. 2006), little is known on how objective measures of activity levels of patients with LBP affect and or relate to LBP outcome measures over time. Activity change within LBP populations undergoing interventions appear to be complex and multifactorial, and within longitudinal research consideration of issues such as psychosocial factors, disability, and pain (Pincus, Santos et al. 2008) to act as potential confounders to the relationship between activity and LBP outcomes need to be considered. The following chapter will systematically evaluate the evidence for the role of PA in patients with LBP and its relationship to LBP outcomes.

CHAPTER IV

The relationship between LBP outcomes and physical activity: a systematic review

4 The relationship between low back pain outcomes and physical activity: a systematic review

4.1 Introduction

The research presented in this chapter investigates the relationship between levels and types of PA in populations with LBP, and with outcome measures (pain, disability, and measures of recovery), both cross sectionally and over time. This review was prompted primarily by the importance placed on restoration and normalisation of activity across all international guidelines for patients with acute LBP, and also from previous review evidence on the positive role of activity advice and exercise in the management of both acute and chronic LBP. No previous review has investigated the associations between activity and LBP outcomes. Therefore this review attempted to find objective evidence for a positive role between measures of activity and outcome in populations with LBP. The results will provide objective evidence for and better inform further prospective research on the relationships between activity and LBP and also inform international guidelines on activity prescription for acute and chronic LBP. Evidence for positive relationships between activity and LBP outcomes would allow prospective examination of the features of activities (intensity, frequency, duration, and type) associated with positive LBP outcomes to better inform clinical management.

The primary aim of this systematic review was to explore the relationship(s) between PA levels in patients with LBP and relevant outcome measures that included measures of LBP-related disability and pain. The secondary aims were to explore whether specific activity levels and or types of activity more strongly related to LBP outcome measures.

4.1.1 Methods

A systematic review was carried out on observational studies which had measured PA levels in patients with non-specific low back pain (NSLBP), and investigated statistical associations with LBP outcome measures. It is recognised that a longitudinal analysis is preferable when seeking predictive or causal relationships between two variables, (Cole and Maxwell 2003), and also within a randomised control trial design (Altman, Schulz et al. 2001). However, cross-sectional studies were also included in this exploratory investigation of relationships between activity and LBP.

4.1.1.1 Search strategy for identification of studies

The following databases were searched independently by two reviewers (PH and BR≈) to obtain relevant studies for this review: OVID, CINAHL, Medline, AMED, Embase, Biomed, PubMed-National Library of Medicine, Proquest, and Cochrane Database (1990 to January 2009). The search strategy used the following text, keyword, and MESH terms in each database: accelerometer, activities of daily living, activity diary, activity level, activity questionnaire, energy expenditure, heart rate monitor, pedometer, physical activities, disuse, and LBP (in appropriate combinations). The search was restricted to studies in the English language.

Citations were first screened by title followed by retrieval of abstract and full text copies of studies when these met the inclusion criteria. Abstracts which made reference to PA measurement in an adult population of patients with LBP were retrieved in full. Reference lists of all full articles were checked for additional studies. Potential studies were then checked independently by two reviewers (PH and BR) for inclusion and any discrepancies discussed. Experts in the field of LBP and activity and those authors whose studies met the inclusion criteria were also contacted in order to identify additional studies. All included studies measured PA in a population with NSLBP, investigated and reported the statistical relationship between free living PA and a validated LBP outcome measure

4.1.1.2 Inclusion criteria

Studies were included if:

1) Design was either a RCT, cohort, case-control, or cross-sectional study.
2) The relationships between free living PA and LBP outcomes were evaluated statistically (with PA accepted as “any bodily movement produced by skeletal muscle that resulted in a substantial increase over the resting energy expenditure” (WHO 2007).
3) PA measures included at least one of the following: DLW, accelerometers, heart rate monitors, pedometers, GPS, interviews, logs, surveys, questionnaires, or activity diaries.
4) LBP measures included one of the following: Quality of Life questionnaires, validated objective measures of LBP disability and functional performance (e.g. Shuttle Walk Test), validated measures of impairment of activities of daily living, pain symptoms

≈ Brigid Ryan

and self-report LBP outcome measures (e.g. Roland Morris Disability Questionnaire, McGill Pain Questionnaire), return to work (Bombardier 2000).

5) Participants were adults (>18 years).
6) Participants had acute, sub acute, or chronic NSLBP (Airaksinen, Brox et al. 2006; Van Tulder, Becker et al. 2006), which did not include the following pathologies: infection, tumour, osteoporosis, Ankylosing Spondylitis, fracture, deformity, inflammatory process, cauda equina syndrome, or spinal surgery.

For the purpose of this review, psychosocial factors (including fear avoidance, locus of control and job satisfaction) were not considered primary outcome measures for LBP, and studies which exclusively assessed the relationship of PA to one of these variables were collected and reviewed separately. Furthermore, studies based upon measures of activity limitation or pain with activity were not included; these specifically measure activities with which the patient is having difficulty or pain, but do not provide a measure of the patient's actual level or type of PA.

4.1.1.3 Data extraction

Data from included studies were independently extracted by two reviewers (PH and BR). If there was disagreement, consensus was reached after a meeting with a third reviewer (DB≠). Data were extracted using a standardised data extraction sheet and tabulated. Data included: study design, number of participants, type of control group (if relevant), demographic characteristics including age and gender, type of LBP (acute, sub-acute, chronic), treatment received (if appropriate), details of PA measurement, duration of PA measurement, duration and timing of follow-up, outcome measures employed including means and standard deviations, attrition rates, and the statistical relationship between PA and LBP outcome measure(s).

4.1.1.4 Quality assessment

The methodological quality of each study was assessed using the Downs and Black checklist (Downs and Black 1998). The methodological qualities of the scored cohort studies (PH and SM[*]) and cross sectional studies (PH and LH[†]) were independently assessed by two reviewers. Any disagreement between these authors was resolved with a third reviewer

[≠] David Baxter
[*] Steve Milosavljevic
[†] Leigh Hale

(DB≠). It is recognised that there is little consensus regarding the optimal method for assessing methodological quality in observational research. Although it has been suggested that the use of quality 'scales' can be potentially misleading in terms of the assessment of bias and confounding factors (Kamper, Rebbeck et al. 2008), the Downs and Black rating tool has been extensively employed as a measure of study quality in non RCT designs (Buscemi, Vandermeer et al. 2006; Malcomson, Dunwoody et al. 2007; Pannu, Klarenbach et al. 2008). The rating tool score was generated by considering each item of the scale on its own merit and consisted of 27 questions, grouped into sections: reporting, issues of internal and external validity, bias and confounding, with scores ranging from 0-31. Articles were not excluded based upon methodological quality.

4.1.1.5 Statistical relationship between physical activity and low back pain

For the purposes of this review, the significance level was set at $p < 0.05$. If studies assessed the relationship between activity and a validated LBP outcome over time, any significant statistical relationships are presented at these time points. Due to the heterogeneity of the statistical methods employed to evaluate statistical relationships between activity and LBP, it was decided to only present the univariate analyses (Kamper, Rebbeck et al. 2008), unless only multiple regression analyses were available.

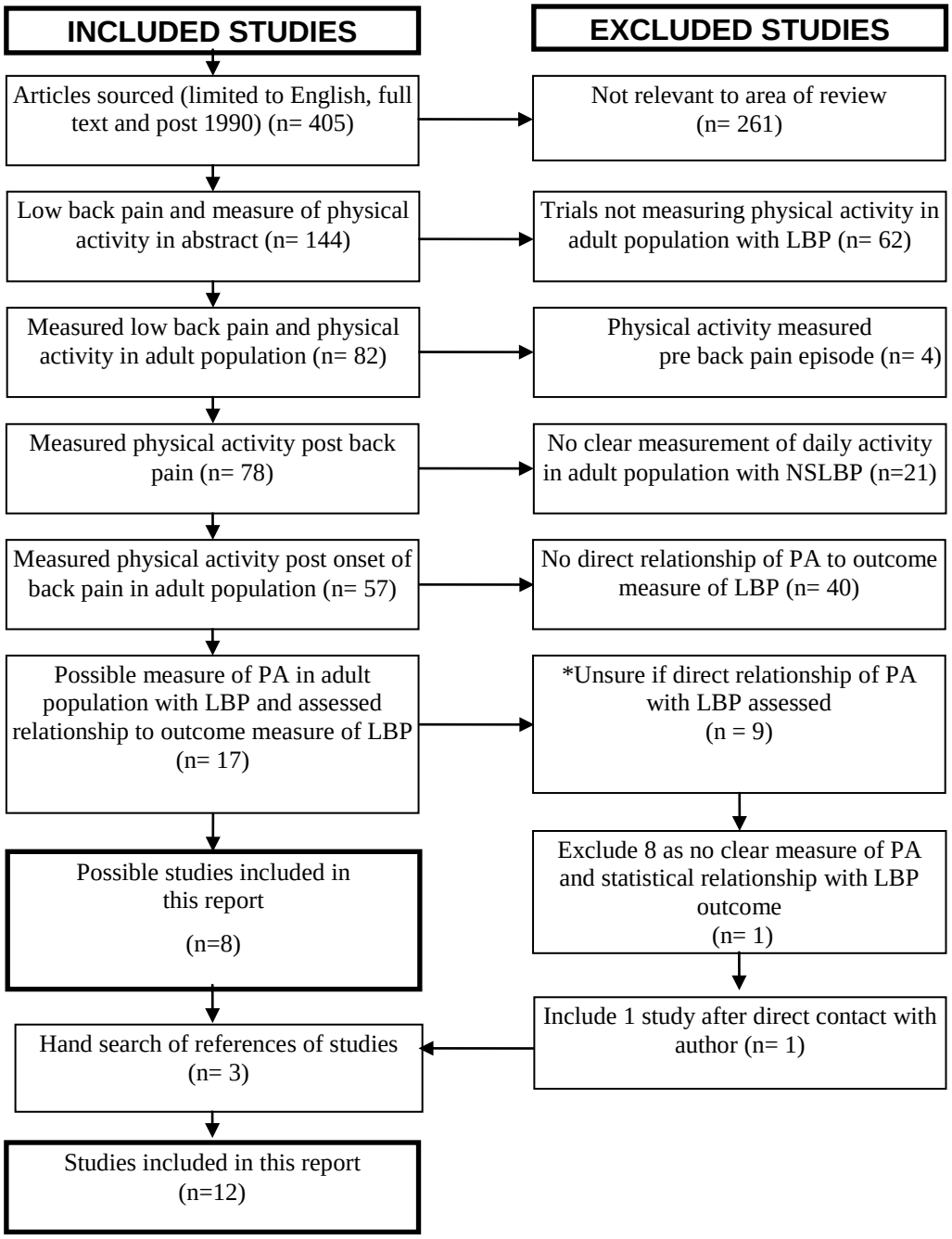

Figure 4-1 PRISMA flow chart of search results from systematic review

4.2 Results

4.2.1 Characteristics of included studies

A total of 144 potential studies were identified of which 78 studies measured PA in a LBP population. Sixty-six articles were excluded for the following reasons: post lumbar surgery, no direct comparison of PA with a LBP outcome measure, measurement of night-time activity only, retrospective measure of PA, mixture of low back, and other pains and no clear measure of free living PA. Nine studies were identified where the author was unsure if direct comparison of a PA measurement was made to a LBP outcome measure, and these were reviewed independently by two reviewers (DH$^{\propto}$ and SMc$^{\in}$) – international supervisory team). Based upon the review and authors' responses to clarification of activity measurement, one further study was included in the analysis (Kuukkanen, Mälkiä et al. 2007).

Twelve articles were included for review that measured PA in an adult population with non-specific LBP, and assessed the relationship with a LBP outcome measure. These included 7 cohort studies (Table 4-1) and 5 cross sectional studies (Table 4-3). Although several of the prospective studies were randomized controlled trials that investigated the effectiveness of various interventions, in each case these studies also investigated the relationship between activity and LBP in a longitudinal cohort design that assessed activity levels within the study population as a whole when assessing the relationship to the LBP outcome measure.

4.2.2 Cohort studies

Only one of the seven studies found a significant relationship between free living activity and a LBP functional outcome (Hurwitz, Morgenstern et al. 2005). The authors reported that recreational activity (combined sports and leisure activities) was inversely associated with both pain and disability at 18 months (Hurwitz, Morgenstern et al. 2005). The odds of clinically meaningful disability were 30% lower among participants in the upper 2 quartiles of the PA distribution than among inactive participants. The remaining six of the seven studies found no significant association between activity levels and LBP disability, pain, or healthcare utilisation.

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$^{\in}$ Susanne McDonough

Results from the quality rating scores (Table 4-1) demonstrated that there was no apparent association between either the total score or the rating within each of the score domains and the reported association between PA and the LBP outcome measure. Studies were generally of moderate to poor quality. Only one of the cohort studies scored highly on the criteria for external validity (Jacob, Baras et al. 2004). Controlling or adjusting for potential bias and confounding issues were scored moderately good to poor for all studies. None of the included studies provided an estimation of power to detect an association between activity and the LBP outcome measure. However, study numbers were relatively large (57 – 1378) with five of the included studies having greater than 300 participants.

4.2.2.1 Types of participants

The majority of studies included participants of working age (18-65 years), diagnosed with non-specific LBP of varying symptom duration (Jacob, Baras et al. 2004; Mortimer, Pernold et al. 2006; Oleske, Lavender et al. 2006; Leonhardt, Keller et al. 2008). Two studies investigated PA within exclusively sub-acute (Bousema, Verbunt et al. 2007) or chronic LBP populations (Kuukkanen, Mälkiä et al. 2007). The levels of disability and pain of participants at entry into the studies were on average moderate (Jacob, Baras et al. 2004; Hurwitz, Morgenstern et al. 2005; Mortimer, Pernold et al. 2006; Oleske, Lavender et al. 2006; Bousema, Verbunt et al. 2007; Kuukkanen, Mälkiä et al. 2007); although one study reported a mixture of disability levels (Leonhardt, Keller et al. 2008), the majority of participants had a low disability rating. Studies used a range of validated LBP outcome measures, with both LBP-related disability and pain being the most consistently measured outcomes (Table 4-1). As recommended, these variables were individually assessed in each of the studies when exploring the potential association with activity (Kovacs, Abraira et al. 2004). It did not appear that level of LBP disability or outcome measure were important characteristics for the positive findings between activity and LBP, since Hurwitz et al found that measures of pain, disability, and the 5-item mental health index ($p < 0.05$) were inversely related to PA (Hurwitz, Morgenstern et al. 2005).

4.2.2.2 Activity measurement

Studies employed a range of PA measures. Although the RT3 accelerometer, as used by Bousema at al, has been validated as a measure of free living physical activity (Rowlands, Thomas et al. 2004; Hendrick, Bell et al. 2009), activity counts are not a standardised unit comparable between studies. None of the studies compared baseline PA measures to comparative measures within other LBP or non-LBP populations. One study employed an

objective measure of PA, the RT3 (Bousema, Verbunt et al. 2007), while all other studies investigated PA with various types of recall questionnaire. Four studies employed self-report questionnaires, which classified various activities into metabolic equivalent of task (MET) energy levels (Hurwitz, Morgenstern et al. 2005; Mortimer, Pernold et al. 2006; Kuukkanen, Mälkiä et al. 2007; Leonhardt, Keller et al. 2008); one study used a simple questionnaire which merely required the participant to state (yes/no) whether they participated in exercise or activity outside work (Oleske, Lavender et al. 2006). Jacob et al. 2004b employed a recall instrument that had been previously validated within a LBP population (Jacob, Baras et al. 2001); this study formed the 1 year follow-up of a cross sectional study (Jacob, Baras et al. 2004a). The reliability and validity of the other PA recall questionnaires had not been previously investigated within a LBP population.

A number of studies employed repeated measures designs to investigate the association between activity and LBP. The only study to report a significant association between PA and a LBP outcome measure (Hurwitz, Morgenstern et al. 2005) specifically focused on leisure time activities, whereby participants reported the number of hours per week spent in walking, light, moderate, and strenuous sport or recreational physical activities at each of the four time points. The only other study which sub-classified the participant's PA in a repeated measures design asked participants how often (on average) they performed regular exercise each week, and classified their exercise activity levels into a low, moderate or high grouping (Mortimer, Pernold et al. 2006). In this study, PA follow up was conducted at the 5-year time point, and the questionnaire included a question about regular physical exercise during the preceding year and at a moment 3 years ago. They reported no association between the exercise grouping and measures of pain and disability at the two time points, but they did report a gender difference within the outcomes whereby the proportion of women reporting previous periods of acute/sub acute pain during the preceding 5 years was highest (66%) in the 'medium' exercise group. Jacob et al. 2004b found no predictive association between PA (classified into a work, leisure and occupational score from a single baseline measurement), and pain or disability at 1 year. Thus, apart from the single study identified above, which indicated a significant association with leisure time activity, other repeated measures studies have failed to find any association with different types of activity and LBP recovery.

The majority of studies employed a measure of the participant's total activity levels and found no association with the LBP outcome measures. Two studies used PA as the main outcome measure (Bousema, Verbunt et al. 2007; Leonhardt, Keller et al. 2008). Bousema et al. 2007

used the PA change score measured with an RT3 accelerometer at two time points one year apart, and reported that PA increased over the year for both patients with CLBP and recovered subjects; although the increase was greater in the non-recovered participants, it did not reach statistical significance. One other large scale study also used PA as the outcome measure within three intervention groups in an RCT research design (Leonhardt, Keller et al. 2008). The authors reported differences in the total volume of self-reported activity between the intervention and control groups, as well as differences in the types of activities, recorded as leisure, sport, and total activities, between the three groups; however overall they found weekly energy expenditure of the participants within the three groups at 6 months or 1 year was not a predictor of development of chronic pain and disability (Leonhardt, Keller et al. 2008).

The measurement of PA within each of the studies required different periods of recall for the participants; one study asked participants at baseline to recall leisure time activities over the preceding year, in order to assign the participants to activity groups. While the Baecke Physical Activity Questionnaire (BPAQ) was generally used to record activity levels over the previous year (Jacob, Baras et al. 2004), some studies did not specifically report the recall period (Kuukkanen, Mälkiä et al. 2007; Leonhardt, Keller et al. 2008). It was therefore unclear what role, if any, this factor played in the association between activity and outcome.

4.2.2.3 Follow- up characteristics

The minimum follow-up period was one year, with the number and scale of follow-up periods ranging from two (at baseline and at one year) (Bousema, Verbunt et al. 2007) to five separate measurements over 5 years (Kuukkanen, Mälkiä et al. 2007). Loss of participants to follow-up in each of the studies ranged from 42% over 5 years (Mortimer, Pernold et al. 2006) to 10% over 18 months (Hurwitz, Morgenstern et al. 2005). Two studies did not report characteristics of those participants lost to follow-up (Hurwitz, Morgenstern et al. 2005; Oleske, Lavender et al. 2006), and a further study did not take into account the potential effects of loss to follow-up (Kuukkanen, Mälkiä et al. 2007).

The rates of chronicity varied significantly between the studies, from 24% (Oleske, Lavender et al. 2006) to 78% (Jacob, Baras et al. 2004) of the sample population at one year. The five year study found relatively high levels of recurrent LBP with only 38% of the men and 36% of the women sampled reporting no disability (Mortimer, Pernold et al. 2006). Hurwitz et al.

2005 did not report on the levels of chronicity, and so the extent to which this factor affected the positive association of activity to the LBP outcome cannot be determined.

Table 4-1 Systematic Review: Characteristics and results of cohort studies

Author	Study Score [27]	Subjects and follow-up	Measurement of Physical Activity	Classification of Physical Activity	Duration of PA measure/ Follow up	Relevant LBP Outcome Measure	Main Results
Bousema et al. 2007	20	124 sub-acute LBP 18-60 yrs (106 completed study)	RT3 Triaxial accelerometer	Total sum of RT3 counts/day (PAL)	7 days Data collected twice: at inclusion (PAL-0) and after 1 year (PAL-1)	PCS, QBPDS, TSK, BDI	No difference in PAL change (PAL-1-PAL-0) in recovered and non-recovered participants. (F = 0.31, p = 0.58)
Hurwitz et al. 2005.	15	610 non-specific LBP 18-70+ yrs	Self reported PA questionnaire	Activity classified as weekly MET values 0; 0.1-10.49; 10.5-25.9; ≥26	Baseline, 6 weeks and 6, 12, 18 months	NRS for pain, RMDQ,	Recreational PA inversely associated with NRS ($p < 0.05$), and RMDQ ($p < 0.05$)
Mortimer et al. 2006	12	459 non-specific LBP 20-59 yrs	Self reported PA questionnaire	Low exercise <2hr/wk at 4 MET. Medium exercise >3hr/wk at 4 MET. High exercise 1hr/wk at 5 MET or higher	Data collection on entry and at 5 year follow-up	Van Korff procedure to classify pain and disability	No significant association between PA and change in pain from baseline to 5-year follow ($p = 0.14$) and PA and change in disability from baseline to 5-year follow ($p = 0.20$)
Oleske et al. 2006	9	352 autoworkers diagnosed with work-related non-specific LBP	PA question-Exercise or physical activities outside work (Y/N)	Y/N	Baseline measurement	No. of health care treatments for LBP at 1 year	PA (outside work) was not significant predictor of LBP recurrence ($p = 0.064$)
Leonhardt et al. 2008	18	1378 patients with non-specific LBP (18-65) 1211 (follow-up)	Freiburger Questionnaire on Physical Activity	Total MET hours/week	Measurements at baseline, 6 months and 12 months	Van Korff procedure to classify pain and disability	No influence of the total EE after 6 months on pain chronification. (No p value reported)
Kuukkanen et al. 2007	11	57 CLBP patients (disabling pain over 3 years); 22-50; 47 at 5 year (follow-up)	MET based questionnaire for the study of PA	The sum and the highest MET values	Measurements at baseline, 3 months, 6 months, 12 months and 5 years	Borg CR-10 Scale, and the ODI	No significant correlation between the Borg CR-10, the ODI and PA at 3 months, 6 months, 12 months and 5 years. (No p value reported)
Jacob et al. 2004a	19	555 non-specific LBP aged 22-70 followed. 367 (66%) follow-up	BPAQ (self-administered)	BPAQ score classification into Occupational, Sports and Leisure time activity score	Baseline measurement	Modified RMDQ SFI and SBI	PA was not an independent predictor of RMDQ, SFI or SBI at 2 months or 12 months (No p value reported)

BDI, Beck Depression Inventory; BPAQ, Baecke physical activity questionnaire CLBP, Chronic Low back pain; LBP, Low back pain; EE Energy expenditure; MET, metabolic equivalent task; NRS, Numerical rating Scale; PA, ODI, Oswestry Disability Questionnaire; Physical activity; PAL, Physical activity level; PAL-0, Baseline activity level; PAL-1, Physical activity level at 1 year;; PCS, Pain Catastrophising Scale, QBPDS, Quebec Back Pain Disability Scale; RMDQ, 24-item Roland Morris Low Back Pain Disability Questionnaire; TSK, Tampa Scale for Kinesiophobia; SBI, Pain Symptoms Bothersomeness; SFI, Pain Symptoms Frequency

4.2.3 Confounding factors included in the association between activity and low back pain

The majority of prospective studies included potential confounders as part of their multiple regression analysis (Table4-2), and only two studies did not assess and or adjust for these factors (Mortimer, Pernold et al. 2006; Kuukkanen, Mälkiä et al. 2007). The only study to find a significant association between activity and LBP in multiple regression analyses (Hurwitz, Morgenstern et al. 2005) included a greater number and range of potential confounders, in terms of behavioural, psychosocial, and other patient characteristics; this was also the only study to include back exercises as a potential confounder.

Table 4-2 Systematic review of activity in low back pain: Confounders reported in multiple regression analyses of cohort studies

Authors	Confounders to the association between activity and LBP
Hurwitz et al 2005	Age, gender, baseline duration of low back pain episode, number of previous low back pain episodes, assigned treatment group, social support, strategy for coping with pain, internal locus of control, baseline mental health index score, baseline LBP and disability levels, muscle strengthening and flexibility exercising
Bousema et al 2007	Depression and perceived activity decline, gender, levels of activity prior to low back pain episode, fear of movement, perceived disability
Oleske et al 2006	Age, gender, work exposure, stress, physical health, occupational risk of LBP
Jacob et al 2004	Baseline pain measures, various lifestyle markers, care-seeking, emotional status markers, perception of general health, and demographic characteristics
Leonhardt et al 2008	Self-efficacy, baseline measures of pain and disability, days of pain in the previous 12 months, Stage of change prior to treatment, baseline PA levels, job satisfaction, depression, fear avoidance levels and gender

4.2.4 Cross sectional studies

Only one of five cross sectional studies reported a significant association between PA and measures of LBP (Jacob, Baras et al. 2004), observing that low sports activity index (SAI) scores contributed to higher scores for most LBP measures (Table 4-3).

4.2.4.1 Types of participants

The five cross sectional studies in the review included patients of working age (18 – 65 years), with a range of LBP durations from sub-acute (Johansson and Lindberg 1998; Verbunt, Sieben et al. 2005) to chronic (Verbunt, Westerterp et al. 2001). Both Jacobs et al. 2004a and Cunha et al. 2002 included patients with a range of LBP durations.

Study quality ranged considerably, particularly in terms of bias and confounding issues, potentially affecting the validity of the results. No studies were powered to investigate associations between activity and LBP. Study numbers ranged from 13 to 555 participants. Although small numbers of participants may have led to a lack of observed associations, the numerically stronger study of Jacob et al. also reported no association between PA and LBP outcome.

One study included participants both with and without LBP to compare and contrast their activity levels (Verbunt, Westerterp et al. 2001), whilst the other studies were performed exclusively on populations with LBP. All studies used validated measures of LBP disability; in some cases measures of pain, depression, and fear avoidance were also employed.

4.2.4.2 Activity measurement

Two studies employed objective measures of PA (Verbunt, Westerterp et al. 2001; Verbunt, Sieben et al. 2005), while three studies made use of various types of PA recall questionnaires. Verbunt et al. 2001 utilised objective and validated measurement of EE in free living, including DLW (Ainslie, Reilly et al. 2003) to sub-classify activity levels into low, moderate, and high; the Tracmor accelerometer was also used, which has demonstrated validity as a measure of free living PA (Plasqui and Westerterp 2007). Another study used the RT3 accelerometer as well as an activity log and the BPAQ to examine the PA in a sub-acute LBP population (Verbunt, Sieben et al. 2005). Two studies included self-reported activity scales (Johansson and Lindberg 1998; Cunha, Simmonds et al. 2002) to assess free living activities. However, neither of these self-reporting instruments has been validated as a measure of activity within a LBP population, and little data are available within healthy human populations as a comparative measure. Jacob et al. 2004a employed the BPAQ (Pols, Peeters et al. 1995) to sub-classify participants' occupational, leisure, and sports activities.

Table 4-3 Systematic Review: Characteristics and results of cross-sectional studies

Author	Study Score [27]	Subjects	Mode of measurement of Physical Activity	Classification of Physical Activity	Duration of measure	Relevant Outcome Measure	Main Results
Verbunt et al. 2001	10	13 CLBP 13 controls 18-60 yrs	Tracmor accelerometer: counts/minute and DLW (PAL = ADMR / RMR)	PAL = ADMR / RMR < 1.60 Low 1.60< PAL < 1.85 moderate >1.85 High	14 days of continual monitoring	RMDQ and VAS	Correlation of PA (Tracmor) and RMDQ: (r = 0.10, p = 0.76) Correlation of PAL and RMDQ: (r =-.06 , p = 0.74)
Verbunt et al. 2005	16	123 sub-acute LBP 18-60 yrs	RT3 triaxial accelerometer Activity log BPAQ	RT3 counts per day (LBP PAL)	Seven days of continual monitoring	VAS score QBPDS BDI	PAL did not contribute to the explanation of disability. PAL vs. QBPDS (p = -0.16)
Cunha et al. 2002	11	51 subjects with non-specific LBP (26-65 years of age)	The self reported PA rating (scale of 0-8)	Scale rating (0-8)	N/A	RMDQ	Correlation of PA with RMDQ (r = -0.04)
Johansson et al. 1998	14	72 participants (18-65) with duration of LBP of at least 4 weeks	The General Activity Scale (self-report questionnaire)	Scale - 18 items perform activities (0 = never, 6 = very often)	N/A	RMDQ	No significant association between PA and RMDQ. Low negative correlation of RM-SW with general activity (r = 0.27, p < 0.05)
Jacob et al. 2004b	17	555 non-specific LBP aged 22-70	BPAQ (self-administered)	BPAQ score classification into Occupational, Sports and Leisure time activity score	N/A	Modified RMDQ SFI and SBI	Significant association between SAI and (Beta, 95% CI) RMDQ (-0.09, -0.1 to -0.02) SFI (- 0.08, -0.14 to -0.02) SBI (-0.06, -0.1 to -0.005)

ADMR, Average daily metabolic rate; BDI, Beck Depression Inventory; BPAQ, Baecke physical activity questionnaire; CLBP, Chronic low back pain; DLW, Doubly labelled water; LBP, Low back pain; MET, metabolic equivalent task; NRS, Numerical rating scale; PA, Physical activity; PAL, Physical activity level; PE, Physical Exercise; QBPDS. Quebec Back Pain Disability Scale; RMDQ, 24-item Roland Morris Low Back Pain Disability Questionnaire; RMR, Resting metabolic rate; SAI, Sport Activity Index; SBI, Pain Symptoms Bothersomeness; SFI, Pain Symptoms Frequency; TSK, Tampa scale for kinesiophobia; VAS, Visual analogue scale

4.3 Discussion

This review found little evidence for an association between free living PA and validated outcome measures of disability or pain in various NSLBP populations. Only one prospective study reported a statistically significant association between activity and disability (Hurwitz, Morgenstern et al. 2005), whereby lower levels of recreational activity were inversely associated, both cross-sectionally and longitudinally, with LBP related disability. One cross sectional study (Jacob, Baras et al. 2004) reported lower levels of self-reported sporting activity were associated with higher levels of pain and disability. The remaining studies (n = 10) found no association between free living PA and LBP outcome measures, either cross sectionally or longitudinally. These findings call into question the role that activity plays in patients with LBP and the accepted clinical guidelines for activity normalisation in the management of LBP (Arnau, Vallano et al. 2006; Van Tulder, Becker et al. 2006).

Although the review included cross sectional studies this research design provides little evidence for causation between two factors (Cole and Maxwell 2003), and therefore exploration of potential associations between activity and LBP outcome measures was primarily driven by results from prospective cohort studies. Overall levels of evidence in this review are not regarded as high due to the absence of high quality RCT studies (Concato, Shah et al. 2000), and the inherent difficulties of limiting potential confounding and bias in observational research (Ranstam 2008). However, it is acknowledged that such levels of evidence hierarchy are based upon intervention studies and that observational studies thus have an important role to play in health care research, particularly when assessing for prognostic or etiological factors (Hoppe, Schemitsch et al. 2009; Merlin, Weston et al. 2009). This notwithstanding, the current review provides moderate evidence (level II) (Hoppe, Schemitsch et al. 2009) that activity, or activity change, in patients with NSLBP is not predictive or associated with LBP outcomes of pain and disability.

4.3.1 Methodological issues

The quality of included observational studies was mixed, and there were a number of research design issues that may affect the validity of the findings. In all of the studies, participants were included as a homogeneous group with no attempt made to diagnose or sub-categorise the patients into subgroups. Although it is recognised that different subgroups within NSLBP may exist (Denison, Åsenlöf et al. 2007; Fritz, Cleland et al. 2007), there is currently little

consensus on the optimal and most valid method to subcategorise such patients (Kent and Keating 2005). It is therefore not known whether specific diagnostic groupings within NSLBP may have different associations between activity and LBP outcomes.

A variety of PA measures were used, the most common being recall questionnaires, the majority of which have not been tested or validated within LBP populations. The activity measures (Freiburger Questionnaire on Physical Activity) employed by Leonhardt et al (Leonhardt, Keller et al. 2008) allow specific comparisons to non-LBP populations (Frey, Berg et al. 1999), while the BPAQ (Jacob, Baras et al. 2004) allows comparison to both LBP and non-LBP populations (Jacob, Baras et al. 2001; Ono, Hirata et al. 2007). The other generic MET-based questionnaires can be used to provide more general comparison to activity levels in other populations, although there are potential issues of bias in that each employs different methods of calculation. Validation and comparison of activity measurement tools between studies and different groups is therefore important, as it allows direct and accurate comparisons of PA measurement and the investigation of change in activity.

It is argued that questionnaires provide the only practical means of assessing activity within large scale populations (Booth 2000); however their limitations and potential bias are also recognised (Neilson, Robson et al. 2008). It is therefore recommended that an objective measure of activity measurement should also be included as a measurement of PA within free living populations with disability (Cervantes and Porretta 2010). This allows a more accurate estimate of the range and types of free living activity (Bassett 2000; Janz 2006), as it has been shown that the ability to accurately assess and determine activity change over time differs between objective and activity recall instruments (Epstein, Paluch et al. 1996; Bassett, Cureton et al. 2000). Correlations between objective measures and questionnaires to assess activity are often variable and activity dependant (Matthews and Freedson 1995; Welk, Thompson et al. 2001; Jacobi, Charles et al. 2009), and it is recognised that each measures different dimensions of activity (Snook, Motl et al. 2009). However, it is also acknowledged that while current health recommendations for PA are based to a large extent on observational research using self-report measures (Blair, LaMonte et al. 2004), the adoption of these has demonstrated significant health benefits to the general population (Ainsworth and Tudor-Locke 2005). One study in the current review employed an objective measure to measure activity at two separate time points (Bousema, Verbunt et al. 2007); however, the predictive association between activity and LBP recovery was not assessed.

The PA recall questionnaires used may have affected the reliability and validity of reported results. The self-report measure employed in a number of the studies did not specify expressly whether the participant should record their activities since the current episode of LBP (Hurwitz, Morgenstern et al. 2005; Oleske, Lavender et al. 2006; Kuukkanen, Mälkiä et al. 2007; Leonhardt, Keller et al. 2008). Therefore it is possible that activity levels prior to the onset of LBP may have been reported by participants, and if different to activity levels with LBP, may have masked the potential affect of PA on recovery. Mortimer et al. 2006 assigned participants at baseline into low, medium, and high exercise groups, based upon reported leisure time activities over the previous year. However, this measurement does not allow for changes or fluctuations in activity levels over time, but treats activity as a relatively stable phenomenon; thus changes in activity over the course of the LBP episode would not be accounted for.

There are also numerous potential confounders to the association between activity and disability (Sallis, Calfas et al. 1999), as well as factors identified as mediators between PA and disability (Perruccio, Power et al. 2005; Motl, McAuley et al. 2009). A number of behavioural and psychosocial variables were accounted for in the multiple regression models; however none of the studies expressly investigated the potential mediating effects of these variables on the association between activity and the LBP outcome. It is therefore possible that the non-associations are due to other behavioural or psychosocial factors, including fear avoidance (Basler, Luckmann et al. 2008), confounding or modifying the association between PA and LBP. This view is supported to some degree by the fact that the only study to report a positive association included a large number and range of potential confounders in the multiple regression analyses.

4.3.2 Physiological and behavioural adaptations to low back pain

The current review found evidence that PA did not affect affected levels of pain, disability, or measures of recovery either cross-sectionally or longitudinally. Previous research which has investigated the effects of LBP on a range of physiological, behavioural and psychosocial measures shows that the interactions are complex. Participants' behaviour can affect the interaction between measures of activity and LBP (Hasenbring, Marienfeld et al. 1994; Crombez, Vervaet et al. 1998; Brox, Storheim et al. 2005). Crombez et al. 1998 investigated the behavioural coping strategies proposed for patients with LBP (Hasenbring et al 1994, Vlaeyen et al 1995) by assessing: the extent to which a LBP cohort avoided movement, or endured the movement until the pain forced them to stop; the amount of attention they paid to

back pain; control of pain; fear of pain, and their fear of re-injury. Based upon responses to these questions they classified participants into avoiders and confronters of PA, whereby avoiders reported more frequent pain in activities and the pain took longer to dissipate after the activity. Avoiders also reported a higher fear of pain, and higher fear of re-injury and consequently more disability and more trouble with physical activities. A more recent study explored the factors that may contribute to deconditioning or loss of fitness in a CLBP population (Brox, Storheim et al. 2005). They found that fear avoidance behaviours were equally prevalent in both a sub-acute and CLBP population, suggesting that these factors appear at an early stage and may contribute to the transition from acute to chronic low back pain. Fear avoidance beliefs for work, disability, and cardiovascular fitness were found to predict return to work over a 1-year period (Storheim, Ivar Brox et al. 2005). These results suggest a potential link between the fear of pain (re)-injury on one hand, and its effect on behaviour and consequently its potential to act as a mediator between PA and LBP outcomes (Burke, Beilin et al. 2008). Previous studies have demonstrated that behavioural factors can mediate the effects of PA on a range of health outcomes (Sallis, Calfas et al. 1999; Perruccio, Power et al. 2005; Molloy, Sniehotta et al. 2009). None of the included studies investigated behavioural factors (including fear avoidance) as potential moderating or mediating factors on the association between activity and LBP, and therefore this is another area to explore.

4.3.3 Potential confounders for longitudinal research

A range of potential confounders were included in multiple regression modelling across the studies. The consistent confounding factors included were age, gender, occupational factors, baseline measures of LBP disability and pain; baseline measures of activity; measures of general health and bio-psychosocial factors (including fear avoidance, self-efficacy). Longitudinal research investigating the potential associations between activity and LBP outcomes should consider inclusion of each of these variables in statistical modelling.

4.4 Limitations

A number of additional studies may have been missed from this review due to the exclusion of grey literature and restriction to English language journals. Although every effort was made to ensure a systematic and rigorous process, due to the multiple study designs and measures of activity, and a number of the studies only investigating activity as a secondary measure in LBP populations, the search terms for PA were not always listed as keywords or contained within the abstract. This review also excluded psychosocial variables as primary

LBP outcome measures, and therefore the effect of such variables on LBP either singularly or in combination is unknown. In order to further consider this argument a further review of the literature is recommended with a focus on the effect of such psychosocial variables.

4.4.1 Potential research directions

It is increasingly recognised that both the types of activities and the variability in activity may be important distinguishing factors for patients with LBP (van den Berg-Emons, Schasfoort et al. 2007; van Weering, Vollenbroek-Hutten et al. 2009). A recent study found that activity fluctuations rather than the mean activity level over time contributed significantly to levels of disability in a cohort of patients with chronic LBP (Huijnen, Verbunt et al. 2009). Therefore further research is required to assess the association between these activity fluctuations within populations with LBP and recovery over time.

The association between LBP and disability has been shown to be modulated by specific performance measures (Di Iorio, Abate et al. 2007) and the effects of PA have been shown to be mediated by factors such as fatigue, mood, pain, self-efficacy, and social support in other populations with disability (Perruccio, Power et al. 2005; Motl, McAuley et al. 2009). In LBP, depression and perceived activity decline predicted activity change over one year in a population with sub-acute LBP (Bousema, Verbunt et al. 2007). Future investigations should focus on the potential moderating affect between activity and functional ability and behavioural factors, and their interactions with factors such as mechanical loading and psychosocial factors (Marras, Cutlip et al. 2009) within the prognostic model for LBP research (Pincus, Santos et al. 2008).

Although some studies assessed the dimensions of PA by using established cut-points for activity-based MET hours of energy, none employed objective and non-objective measures of activity to assess change in the various dimensions of activity (intensity, frequency, duration) over time (Bouchard 2001). Activity research measurement should also consider classification and investigating change in the types of activity including sleep, light, moderate, and heavy intensity, as well as leisure and sports activities, household chores, and occupational activity (Jacobs Jr, Ainsworth et al. 1993). Consequently, there is a need to explore the potential predictive association between LBP recovery and PA change measured with both an objective measure and recall questionnaire in a repeated measures design (Spenkelink, Hutten et al. 2002). Such measures should be validated within both normal and LBP populations to allow comparisons.

Results from the current review do not provide evidence for the role of PA in LBP disability or pain levels. The search for dose response associations between activity and a range of health outcomes is recognised as important (Lamonte and Ainsworth 2001) particularly in terms of exploring factors such as the nature of the association, evidence of a threshold, and whether the association varies with the type of outcome measure employed (Bouchard 2001). There are a number of other factors required to establish a causative role in health, including the strength of association across various studies; demonstration of a temporal sequence; and a biological mechanism to explain the association (Bauman, Sallis et al. 2002). The models of deconditioning in LBP remain contentious, and there is little evidence from this review for an association between activity and LBP disability and recovery. However the lack of high quality prospective research, and the validity issues associated with the included studies, indicates that there is still much to explore in this area.

4.5 Conclusion

This systematic review evaluated the evidence for the association between free living physical activity in patients with NSLBP and LBP outcomes. Findings do not support an association between activity and LBP outcome measures: only one of the included studies reported a significant association between leisure time activity levels and LBP recovery. However, the review also highlighted the difficulties and complexities of assessing and accurately measuring activity in free living, and the scarcity of studies which have employed objective measures of activity to prospectively investigate its association with LBP in the community. The known health benefits of physical activity support the current clinical guideline recommendations for patients to maintain and restore their activity as part of the overall management of LBP. Therefore, further research is required to definitively evaluate the role that the various dimensions of physical activity play within specific groups of patients with LBP in terms of its outcome and prognosis.

4.5.1 Planned study design

This review of observational studies did not find evidence for PA playing a role in low back recovery or levels of pain and disability. However, this review highlighted the requirement to more effectively evaluate the role of activity within various LBP populations.

Based upon the review results a number of recommendations can be made for the development of a research study design to investigate the potential predictive associations between activity and recovery from LBP.

There is a necessity to develop prospective research into how activity changes over time within specific LBP population (chronic and acute LBP), employing a repeated measures design including an objective measure of activity and a range of activity measures. Such research should aim to:

- Investigate potential changes in the various dimensions of PA (type, frequency, intensity and variability) and the predictive association to low back outcomes and recovery over time
- Include measurement of identified potential confounders to the association between activity and LBP outcomes (including behavioural and psychosocial variables)

Physical Activity is proposed to be important in the secondary prevention of a range of chronic diseases (Karmisholt and Gotzsche 2005). Secondary prevention of chronic LBP remains a health care and research priority (Van Tulder, Koes et al. 2002). In order to best assess the potential for physical activity to play a role in the secondary prevention of chronic LBP requires that a non-chronic LBP population be studied (symptom duration < 3months) prospectively to explore potential associations between physical activity and LBP outcomes.

The proposed research will investigate whether associations exist between objectively measured PA and functional disability in an acute LBP population. Evidence for such effects will also allow assessment of the associations between LBP recovery and reoccurrence at one year, occupational activity, and objectively measured free living activity. The following chapter investigates the reliability and utility of the RT3 triaxial accelerometer as a measure of free living activity to assess its potential use for longitudinal assessment of PA within populations with LBP.

CHAPTER V

Pilot study investigating sources of activity variance and utility of an RT3 for measurement of activity in free living

5 Pilot study investigating sources of activity variance and utility of an RT3 for measurement of activity in free living

5.1 Introduction

The current chapter outlines the methodology, results, and critical discussion of a repeated measures analysis of RT3 activity data within a normal population, in order to estimate the sources of variance and causes of data loss over the repeat measurements.

The accurate measurement of PA in free-living is complex, and the design, analysis and interpretation of free-living PA within health-related studies is dependent on the reliable estimation of daily and weekly fluctuations (variance) in PA levels (Matthews, Ainsworth et al. 2002). Estimation of the sources of variance and patterns of PA in free living with a specific PA measurement tool are therefore an important consideration (Gretebeck and Montoye 1992). Measurement of such sources of variance allows estimation of the reliability of the measurement tool, and also calculation of the number of days required to accurately estimate PA levels within specific populations (Coleman and Epstein 1998; Matthews, Ainsworth et al. 2002). Stability and reliability are recognised as important constructs for a measurement tool in free living (Kochersberger, McConnell, et al. 1996). No repeated measures design studies have investigated the stability and sources of variance in free living PA as measured with the RT3, as well as utility and causes of data loss.

The RT3 triaxial accelerometer (StayHealthy Inc., Monrovia, CA) has been used as a measure of PA in numerous free-living and health-related studies (Kozub, Oh et al. 2005; Kavouras, Sarras et al. 2008). However, reliability and validity studies in controlled environments demonstrate significant inter- and intra- monitor variability (Powell and Rowlands, 2004, Esliger and Tremblay, 2006). While studies have recommended that reliability of the RT3 be tested over longer periods of time in the field in free living environments (Powell and Rowlands 2004), few studies have employed a repeated measures design to investigate the stability of the RT3 to measure PA in a healthy, free-living population. A repeated measures design has been recommended in order to investigate sources of activity variance (Levin, Jacobs et al. 1999) as it allows for the assessment of how much within and between-subject daily, weekly, and monthly fluctuations contribute to activity variation over time.

The magnitude and cause of data loss, particularly for repeated measures longitudinal studies require careful consideration. Previous literature has discussed data loss due to technical failure of activity monitors within the laboratory (Metcalf, Curnow et al. 2002; Rowlands, Stone et al. 2007), and during intervention or observational studies in the community (Williams, Klesges et al. 1989; Welk and Corbin 1995; Sirard, Melanson et al. 2000; Verbunt, Seelen et al. 2005). Battery failure or dislodgement is frequently reported as a cause of data loss (Conn, Minor et al. 2000; Steele, Belza et al. 2003). However, the magnitude or relevance of this data loss is infrequently discussed.

Studies have shown that adherence to wearing activity monitors decreases over time, thereby increasing requirements for further wear time. Repeated periods of data collection and increasing the number of days of consecutive wear are factors which have been found to negatively affect data collection in specific populations (Van Coevering, Harnack et al. 2005; Rousham, Clarke et al. 2006). Although strategies to improve data collection including regular contact and participant incentives have been trialled, the long term effectiveness of these strategies is unclear (Trost, McIver et al. 2005).

Loss of data due to either technical failure or adherence to wear time will negatively impact daily and weekly estimates of monitor reliability, and will necessitate an increase in the number of days of data collection (Trost, McIver et al. 2005). Determining the fewest number of days required to monitor an individual's PA with an estimated level of reliability is important for study design, and dependent on knowing the causes and relevance of data loss.

No studies have investigated the stability and sources of variance in PA as measured with the RT3, as well as utility and causes of data loss in a repeated measures design.

The purpose of this study was to:

I. Explore the weekly stability (week one, four, and eight) of the RT3 to measure PA; and,
II. Investigate the primary sources of activity variance, in a repeated measures design using an RT3 in a healthy population.

Secondary aims were to:

i. Explore the magnitude and reasons for any observed RT3 data loss over the three week periods of data collection;

ii. Identify specific utility issues of the RT3 and their potential impact on the amount of days of activity required to estimate activity within this population

The results will allow evaluation of the day-to-day and week-to-week variation in activity measured by the RT3 accelerometer, its utility, as well as identified aspects and reasons for data loss. These will enable determination of the number of days of PA measurement necessary to give an accurate and reliable estimate of habitual PA over time for future longitudinal studies, in order to achieve a balance between adherence to wearing the monitor and variance of measurement.

5.2 Methods

A longitudinal repeated measures design was employed.

5.2.1 Participants

A pilot study aimed to recruit approximately 20 participants from two research centres affiliated with the University of Otago (approx 10 participants at each centre). The primary investigator (PI) for each centre (PH and MPδ) was responsible for selection, recruitment, and data collection. Data from twenty participants (within the repeated measures design) was considered sufficient to evaluate sources of variance and utility issues. A convenience sample of participants was recruited by public advertising via Otago and Wellington University e-mail distribution over a four week period during July and August 2007. The following inclusion criteria were used: (a) in general good health, with no current or past history of pre-existing medical conditions which limited physical activity; (b) able to walk independently around the home and outside without appliances; and (c) aged between 18 to 65 years of age. This age range was chosen as representative of the working age population in New Zealand. Exclusion criteria included: (a) inability to remember to wear the RT3 daily; (b) an inability to construct a handwritten record of their daily activities; (c) a history of current or past medical problems which prevented usual day-to-day activities; and, (d) an inability to walk independently within the home and outside.

5.2.1.1 Consent procedures.

Ethical confirmation (Appendix page 196 and pages 198-200) and Māori consultation (Appendix page 197) were undertaken. Each potential participant was interviewed by the PI at

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each centre. Following consent, baseline data were collected regarding participant height (stadiometer, Seca 214, portable) and weight (Seca Alpha Model 170); Occupation; primary activity participation; and days per week involved in organised home, social and work activities (Appendix pages 201-204). Each participant's sex, height, and weight were downloaded onto the RT3 via the StayHealthy software^{TM}.

5.2.1.2 Measures

The main aims of the study were to measure the reliability and stability of measurement of PA in free living with the RT3 triaxial monitor, and secondary to this to investigate the utility of the RT3 to measure PA in a repeated measurement design. Mode 4 of the RT3 allowed storage of one week of VM data within the memory limits of the RT3 device. All of the nine RT3 units used for this study underwent testing with standardised laboratory-based walking activities. Each monitor was tested individually, and a single person repeated the activities three times for 10 minutes each. The nine RT3 monitors showed an average within-RT3 CV equal to 7.2% and the standard error of the mean (SEM) was 3.6 counts/min. Between-RT3 CVs and SEMs were 6.3 % and 3.2 counts/min for walking. One RT3 unit consistently recorded lower values than the other monitors in all activities; this device was withdrawn from the study. The remaining eight RT3 units were divided evenly between the two research centres.

Participants also completed the 7D-PAR (Sallis, Haskell et al. 1985) at the end of each monitoring period. The 7D-PAR required participants to recall the level (mild, moderate, vigorous) and amount of PA they completed the previous week. Prior to completion of the 7D-PAR, participants were instructed that "normal walking" and its equivalent represented moderate activity; vigorous housework and heavy manual labour were the equivalent of hard work; and running was classified as very hard. The 7D-PAR was self-completed and the total physical activity energy expenditure (PAEE) calculated in kcal/kg as per Sarkin et al. 1997. Participants were also asked to complete an activity diary (Hale, Pal et al. 2008) detailing their main activity each waking hour, and were also advised to record in their diary the time and reason for any removal of the RT3 (Appendix pages 229-232).

At the completion of the three monitoring periods, participants completed a utility questionnaire (Hale et al., 2008) which asked them to comment on the convenience, acceptability, and any difficulties associated with wearing the RT3 (Appendix pages 203-204). The questionnaire consisted of four statements where the level of agreement with the

statement was marked on a 100mm anchored line. Two closed question asked if participants would be agreeable to wear the RT3 again for future research projects, and if they felt the monitor was user friendly. A final open ended question asked participants for any further comments (Appendix page 204).

5.2.2 Procedures

5.2.2.1 Baseline measures

The RT3 was clipped onto the participant's belt or waistband in the centre of the lower back, and they were advised to keep the monitor in this position during all waking hours, apart from water-based activities and contact sports (Appendix page 248). If the monitor caused discomfort in this position, participants were advised to shift it to the lateral right pelvis, to note the change of position in the activity diary, and to return the monitor to its original position when appropriate. Participants were advised that the monitor should be placed in a prominent and clearly observable position overnight to avoid forgetting to wear it the next morning. Each participant was contacted twice (via electronic-mail, short message service/text, or telephone, depending on preference) during the week to determine any utility issues with the RT3, and to encourage adherence to the protocol.

5.2.2.2 Follow-up (weeks one, four and eight)

At the end of the first week the daily activity log was collected, and participants completed the 7D-PAR questionnaire. The RT3 was removed and data downloaded using the StayHealthy^{tm} software. This procedure was repeated for each participant approximately three and seven weeks later (i.e., weeks four and eight). These subsequent data were collected during a working week similar in tasks and duration to that of the first week, and within a two month period to minimise for seasonal variation. Participants were allocated the same RT3 for each of the three weeks of assessment. At each new testing session, weight was re-measured and recorded. Following data collection and download, each completed data set was inspected, cleaned, categorised, and coded for statistical analysis.

5.2.3 Statistical analysis

5.2.3.1 Data Management

RT3 data were checked for accuracy and completeness. Each participant was required to have a minimum of 10 hours of RT3 data on five or more days of the week, including one weekend day, to be included in the analysis (Gretebeck and Montoye 1992). All accelerometry data

were downloaded via StayHealthy^{tm} software into an Excel spreadsheet. A review of all accelerometer data was undertaken to determine the number of days of accelerometer data recorded, to ascertain sleep times, RT3 removal, and to identify possible RT3 malfunctions (Alhassan, Sirard et al. 2008). Data were then scanned for non worn periods, and wear time was determined by subtracting non wear time from 24 hours. Non wear was defined by an interval of at least 60 consecutive minutes of zero activity intensity counts, with allowance for 1-2 min of counts between 0 and 100 (Troiano, Berrigan et al. 2008). Such data were deemed to be 'missing' (Ward, Evenson et al. 2005). Estimates of data loss and the reasons for any activity data loss were also investigated (Paul, Kramer et al. 2008), as it is recognised that such missing data can affect the internal validity of the activity measurement.

5.2.3.2 Analyses

Descriptive statistics were calculated for demographic data, RT3 VM counts, and 7D-PAR PAEE for each week of monitoring. Each participant was required to have a minimum of 10 hours of RT3 data on five or more days of the week to be included in the analysis (Gretebeck and Montoye 1992).

RT3 wear time was calculated by subtracting the hours of non-wear as recorded in the participant diary from 24 hours (Troiano, Berrigan et al. 2008). Periods during which excessively low RT3 counts were identified (60 minutes of continuous VM counts of 10 counts/min or below) (Buchheit, Platat et al. 2007) were cross referenced to the activity diary, and the hours and reasons for RT3 removal manually transferred onto an Excel sheet for descriptive analysis. Hours of sleep, as recorded in the activity diary, were not considered as activity data, and were therefore not included in any missing data analysis.

5.2.4 Weekly stability and sources of variance of the RT3

There were three weeks of data (weeks one, four, and eight), with daily measurements for the RT3 and the 7D-PAR questionnaire. Plots of the mean and standard deviation of the RT3 VM counts per 24 hour period, by day of the week and by weeks, were used to illustrate the variability in readings. A mixed linear model was used to quantify variability due to variation by day of the week, and by three different weeks, in relation to subject-to-subject variability, by variance components. Finally, 100 random samples of measurements from each of the three weeks of the study were taken from two to six days within each week. The mean of these samples was calculated for each participant, giving a simulation of data that would result from measuring each participant over this time frame.

For each week, the variance of these simulated data was compared to the variance of the mean of seven days of measurements for each week. The ratio of the variances of the samples of a few days to that for the full seven days was an estimation of the inflation in sample size needed for a randomised controlled trial based on variance from fewer days of wear compared to a full seven days.

Descriptive statistics were used to analyse: 1) wear hours from the RT3; 2) the reasons for data loss; and 3) to summarise responses from the utility questionnaire. In order to estimate total time associated with missing RT3 data, the hours of RT3 wear time, as recorded in the diary, were calculated.

5.3 Results

Two convenience samples totalling 21 participants (13 women, 8 men) were recruited and studied in Dunedin (n = 10) and Wellington (n = 11) respectively. The demographic data of these participants are shown in Table 5-1.

Table 5-1 Baseline characteristics of participants

Characteristic	Mean (SD)	Range
Age (years)	35 (14)	19 to 61
BMI (kg/m2)	23.9 (2.2)	20.2 to 27.6
Weight (kg)	71 (7.7)	55 to 90
Height (cm)	172 (6.7)	161 to 183
Hours of work a week	35 (14.3)	0 to 55
No. of days involved in organized activity	3.5 (1.9)	0 to 7

Figure 5-1 shows a box-plot of mean daily activity (RT3 VM units X 10^3) across the 7 days of monitoring over the 3 repeat weeks, with greater variability noted on the weeks 1 and 3 compared to week 2.

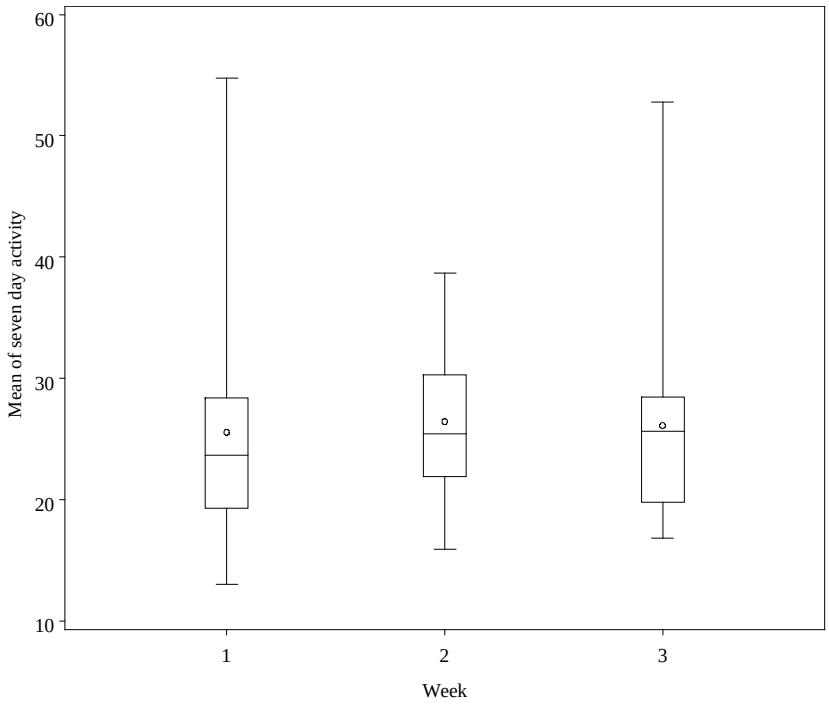

Figure 5-1 Box plot of Weekly means of RT3 VMU X10^3

Table 5-2 Mean RT3 VMU X10^3 for each week by participant

Participant	Week 1	Week 2	Week 3
1	27.4	24.0	26.0
2	17.4	16.7	18.6
3	23.7	28.0	27.7
4	35.4	37.6	52.8
5	26.3	25.6	27.1
6	24.3	30.3	16.8
7	35.9	38.7	24.0
8	25.8	24.1	29.7
9	19.8	22.6	25.7
10	18.4	23.9	19.8
11	13.0	31.6	22.4
12	20.8	15.9	19.2
13	28.4	33.5	36.5
14	19.3	21.6	20.6
15	23.5	26.5	28.5
16	17.3	25.4	NA
17	30.6	28.8	16.9
18	36.4	21.9	24.4
19	54.7	36.3	33.9
20	15.1	21.5	NA
21	23.4	21.4	25.8
Mean	25.6	26.5	26.1
SD	9.4	6.3	8.4

Weekly mean RT3 VM count for each participant, and the group means for each of the three weeks of monitoring demonstrate that there was little difference in the mean group activity levels across the three weeks of monitoring (Table 5-2) Table 5-3 presents the mean activity by day of the week for each participant. The mean activity across each of the days of the week ranged from 27 X 10^3 activity units on a Monday to 24.3 X 10^3 activity units on a Wednesday.

Table 5-3 Summary by day of the week, of RT3 VMU X 10^3 for all participants

Day	Mean (SD)	Inter-quartile range	Range
Monday	27.2 (13.6)	17.1 to 31.7	11.1 to 81.8
Tuesday	26.4 (13.1)	17.6 to 29.7	10.2 to 67.7
Wednesday	24.4 (10.5)	16.8 to 29.4	4.6 to 54.8
Thursday	26.7 (11.1)	18.0 to 31.9	5.4 to 60.1
Friday	26.1 (10.8)	20.1 to 31.8	11.4 to 70.9
Saturday	25.8 (15.7)	15.8 to 32.1	3.5 to 86.1
Sunday	25.8 (19.8)	15.8 to 28.2	4.3 to 129.1

Table 5-3 summarises the descriptive statistics for RT3 activity counts by day across the three weeks of monitoring. The table shows that there was little difference in the mean counts

across the 7 days of monitoring, but that there were differences in the SD and the range between days: a phenomenon particularly noted at weekends.

Table 5-4 Summary by week, RT3 VMU X 10^3 for all participants

Week	Mean (SD)	Inter-quartile range	Range
One	25.6 (13.9)	17.0 to 31.6	4.1 to 97.5
Two	26.5 (14.5)	17.3 to 31.8	3.5 to 129.1
Three	26.2 (13.0)	17.1 to 31.0	4.6 to 86.1

Table 5-4 presents the mean group counts for each week. There was little difference between the mean group counts over the three weeks of monitoring (Table 5-4). However, the SD and range in RT3 VM counts increased in week two demonstrating greater within-subject variability during this week.

Variance components attributable to day, week, and subject variability are presented in Table 5-5. These results confirm that the majority of the variance in activity across the three weeks of monitoring was due to subject variability in activity, followed by the week of monitoring, and the day of the week.

Table 5-5 Variance components: All data

Component	Value	Percentage of Total
Day	27.4	14.7
Week	35.8	19.2
Residual (Participant)	123.4	66.1
Total	186.6	

Approximately 65% of the variance in activity was due to within-subject variance, and approximately 35% due to the day of the week in weeks 1 and 3. However, in week 2 almost 95% of the variance in activity was due to within-subject factors, and only 5% due to day of the week (Table 5-6).

Table 5-6 Sources of PA variance attributable to the subject and day of monitoring

Component	Value	Percentage of Total
Week 1		
Day	70.8	36.3
Residual (Participant)	124.5	63.7
Total	195.3	
Week 2		
Day	11.8	5.6
Residual (Participant)	197.5	94.4
Total	209.3	
Week 3		
Day	53.9	31.5
Residual (Participant)	117.0	68.5
Total	170.9	

The ratio of variance for a randomly sampled number of days against the variance for the full 7 days is presented in Table 5-7. In weeks 1 and 3, the use of 4 days from the 7 days gave an optimal ratio, approximating 1, which was not significantly changed by the addition of extra days. However, in week 2 a sample of 6 days from the 7 recorded days was required to give a similar ratio.

Table 5-7 Ratio of a few days random sample variance to full seven day variance by week

	Ratio of variance of a few days mean readings to full seven days mean reading: Mean (SD)		
Number of days randomly sampled	Week 1	Week 2	Week 3
2	1.5 (0.5)	2.7 (1.1)	1.7 (0.7)
3	1.3 (0.4)	2.0 (0.4)	1.4 (0.5)
4	1.1 (0.3)	1.3 (0.2)	1.1 (0.3)
5	1.1 (0.2)	1.3 (0.2)	1.1 (0.3)
6	1.1 (0.1)	1.1 (0.1)	1.0 (0.2)

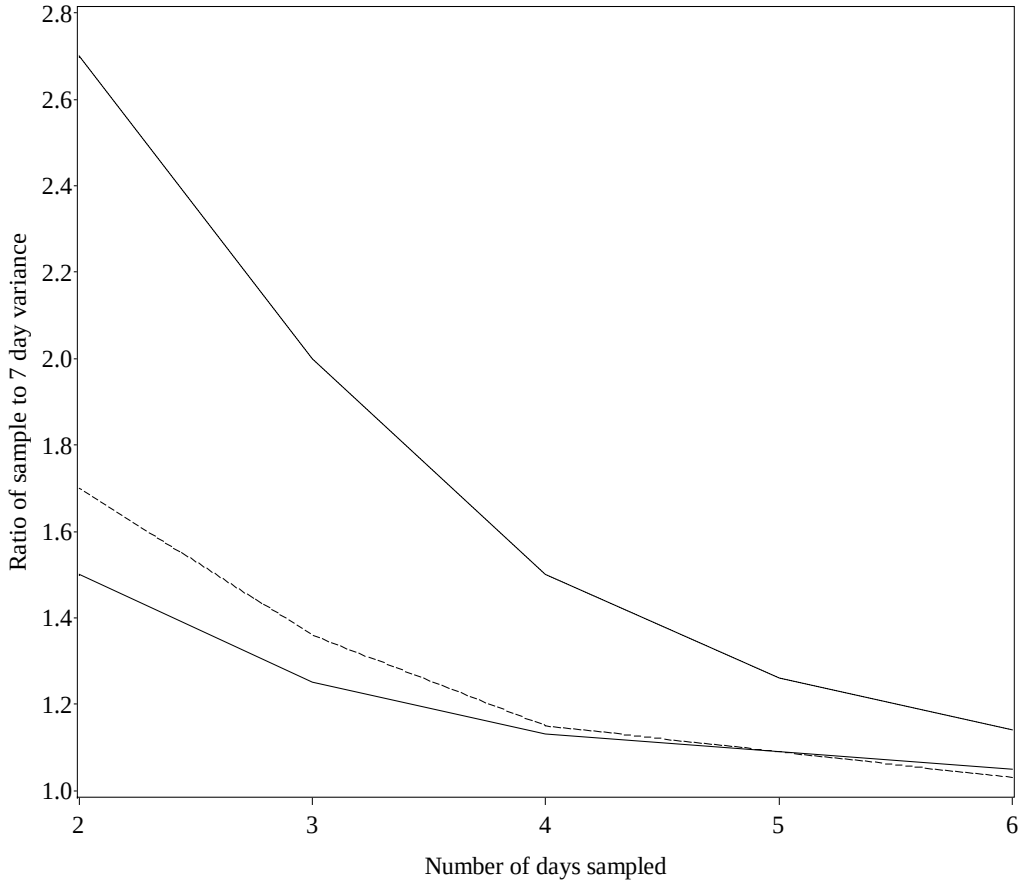

Figure 5-2 Ratio of sample to 7 day variance by week

Solid: Week 1

Short dash: Week2

Long dash: Week 3

Employing the ratio of a sample day variance to number of days sampled demonstrated that four days of monitoring give a reasonable estimate of variance in activity if data from weeks 1 and 3 were used (Figure 5-2). However, week two required at least 6 of the 7 days to be included to give an accurate estimate of the variance in activity over the 7 days.

5.4 Utility results

Table 5-8 depicts the total weekly and mean daily hours of RT3 wear time (SD) of collected activity data, the number of participants with 100% adherence, and the number which met the inclusion criteria of 10 hours of RT3 data on at least five or more days, including one weekend day. The mean (SD) hours of wear time per individual per week was reasonably consistent over the three weeks, with means of 101 (7.3), 100 (10.3), and 98 (10.0) hours of

data recorded for week one, two, and three respectively; however, the variability of wear time increased from week one to weeks two and three.

Table 5-8 Number of participants with minimum inclusion criteria

Week	Total hours/week wear time	Mean hours/day wear time (SD)	No. of participants with ≥10 hours of data on 5 days	No. of participants with ≥ 10 hours of data on all 7 days
1 (n = 21)	2134	14.5 (1.0)	21	21
2 (n = 21)	2103	14.3 (1.5)	19	18
3 (n = 19)	1862	14.0 (1.4)	19	13
Total	6099			

The number of participants obtaining at least 10 hours of data on all days of the week declined from week one to week three (Table 5-8). All participants met the inclusion criteria for a minimum of five days with 10 hours of RT3 data collected in weeks one and two; 91% of participants (n = 19) achieved this in week three. Two participants in week three lost all data due to technical failure of the RT3. Ninety three hours (13.3 average hours of daily wear time), and 107.5 hours, (15.4 average hours of daily wear time), were calculated to be lost for these two participants respectively in week three.

Table 5-9 Hours and reason for the RT3 data loss across the 3 weeks of monitoring

Participant self-report in diary	Forgot (hours)	Aesthetics (hours)	Sports (hours)	Water Damage (hours)	Discomfort (hours)	Fell off or afraid of losing (hours)	RT3 holster Breakage (hours)	Lost RT3 (hours)	Total hours of RT3 data loss (hours)
Week 1	18	8	4	0.5	9	1.5	0	0	41
Week 2	63	4	4.5	0.5	1	6.5	3	0	82.5
Week 3	59.25	7.5	6	0.5	4	6.25	4	48	135.5
Total	140.25	19.5	14.5	1.5	14	14.25	7	48	259

In total 6535.8 hours of RT3 activity data were collected from participants (n = 21) during awake hours as recorded from the activity diaries. The RT3 contained no descriptor of activity data for an estimated 443.3 (6.7%) hours as determined from a review of the activity diaries. RT3 activity data loss increased from 41.0 hours in week one, to 82.5 in week two, to 135.5 hours in week three. Table 5-9 shows the hours and reasons for data loss over the three weeks of monitoring. Most of the non-recorded activity hours occurred in weeks two and three (91.0%). Both monitor (48.4%) and participant factors (52.8%) contributed equally to the 443.3 hours of data loss. Specifically, technical malfunction in week three accounted for 200.5 hours (45.2%) of the 443.3 total hours of data loss, while forgetting to wear the RT3, over the three weeks, accounted for 169.6 hours (38.2%) of the total. Data loss due to participation in sports and water-based activities were fairly uniform over the three recorded weeks, and accounted for 18 hours (4.2%) of data loss.

Table 5-10 RT3 utility questionnaire data (n = 21)

Question	Mean Score on 100mm line (± SD)a
1. The RT3 was acceptable to wear for seven days	82 (18)
2. It was easy to remember to wear the RT3 daily	89 (17)
3. The RT3 interfered with daily activities	24 (20)
4. The RT3 was annoying to wear	23 (20)
5. Would you wear the RT3 again for research	Yes = 21 (100%)
6. Was the RT3 user friendly	Yes = 17 (81%), Maybe = 4 (19%)

A high score indicates increasing agreement with the statement and low score indicates increasing disagreement except for questions 5 and 6 which required a yes, no or maybe answer.

The majority of participants felt that the RT3 was acceptable to wear (n = 20), and easy to remember to put on (n = 21) (Table 5-10). Sixteen participants responded to the open question: in total 37 comments were made. Discomfort due to the position of the RT3 on the

back, especially with sitting at work or driving, was reported by 12 of the 16 (75.0%) responding participants, and was the strongest theme to emerge from the open question. Five of the 16 responding participants (31.3%) mentioned shifting or removal of the RT3 during specific manual aspects of their job for periods of up to one hour (network engineer, physiotherapist, personal trainer, and two students).

5.5 Discussion

This study investigated variance components and the stability of the RT3 triaxial accelerometer to measure PA behaviours on three separate weeks, over an eight week period, and also assessed the utility of the RT3 by investigating the magnitude and reasons for data loss compared to the total number of activity hours collected. Results indicate that mean activity varied little by day of the week across the three weeks; however, the variance of activity varied considerably by day of the week, especially on Saturday and Sunday. Within-subject variance was the main source of both daily and weekly variance for PA measurement with the RT3, and 34% of the variance of activity was due to day-to-day and week-to-week variation. The utility of the RT3 was good and most participants found the RT3 acceptable to wear for the seven days, corroborated by the high hours of daily wear. Total data loss was estimated to be approximately 6.7% (443.3) of the 6535.8 hours of RT3 data collected. Technical factors (48.4%) and participant factors (52.6%) were equally responsible as causes of RT3 data loss.

These results demonstrate that four days of randomly sampled days give an accurate and reliable estimate of activity and variance in activity in a normal healthy population. Previous research investigating the stability of the RT3 in participants following cardiac surgery reported moderate stability of PA measurement over two days of measurement (ICC = 0.79), and very high stability over four days of data collection (ICC = 0.92) (Hertzog, Nieveen et al. 2007). Another study found very high stability of measurement of PA with the RT3 over four days within a disabled population (ICC =0.88 - 0.92) (Lores, Garcia-Rio et al. 2006). The variability in the ratio of variance in PA in the current study, particularly noted in week 2, is probably attributable to an increased variation in daily and weekly activity when compared to those with disability. This factor, along with differing methods of estimating reliability and variance in activity between studies, may explain the differences in the estimates of variance in activity (Hertzog, Nieveen et al. 2007).

Variability in activity was altered by day of week, whereby greater variability in activity was found on weekends compared with weekdays. No previous research has assessed variability of activity comparing weekdays to weekends with the RT3. Previous research employing accelerometry has found greater variability in activity at the weekends in healthy cohorts (Gretebeck and Montoye 1992; Baranowski, Smith et al. 1999; Behrens and Dinger 2007), and also significant differences between weekend and weekday data in children (Trost, Pate et al. 2000; Mattocks, Leary et al. 2007). Results from this study show variability in activity, particularly on a Sunday, was greater when compared to weekdays. A study of activity in young adults employing a triaxial accelerometer also reported greater weekend variability of PA (Buchowski, Acra et al. 2004). The current study did not have sufficient numbers to analyse for sex differences in PA variance. Results corroborate the recommendation that PA measurement should include a weekend day of data due to the differences in variability (Gretebeck and Montoye 1992).

Within-subject variance was the greatest source of variance for both daily and weekly measures across all three weeks of monitoring. The substantially increased within-subject variance in week 2 is difficult to explain, and may be a factor of the relatively small sample size, and the activity levels of a young, active, and working population. Previous research found between-subject variance measured from TriTrac-R3D VM counts was the largest source of variance in a group of sedentary individuals (Coleman and Epstein 1998). Conversely, within-subject variability, measured with a uniaxial accelerometer, was the largest source of variance within a healthy population over a one-year assessment period (Levin, Jacobs et al. 1999). In addition, between-subject differences accounted for the majority of variance in a healthy population (60%) employing a uniaxial accelerometer over three weeks, and within-subject variability was the largest source of variance for time spent in physical inactivity (Matthews, Ainsworth et al. 2002). Differences in these variance findings may be explained by a number of factors including: the types, frequency and patterns of activities of the participants (Levin, Jacobs et al. 1999); sex and age of the participants (Matthews, Hebert et al. 2001); the activity output and type of measurement tool employed (Matthews et al., 2001, Coleman and Epstein, 1998); and, importantly, the amount of error in the measurement system (Baranowski, Smith et al. 1999). The variance patterns reported in this study show consistently that within subject variability is the largest source of variation in activity across repeat weeks of testing with the RT3 within a healthy active population.

5.5.1 Utility and data loss

The current study found high levels of wear time with an average of 90.0%, 89.0% and 87.5% of an average 16 hour day containing activity data (Macfarlane, Lee et al. 2006) over the three separate weeks of study. Similar percentages and hours/day of wear time have been reported previously, within a free living population, over a single 7 day period with a waist mounted activity monitor (Macfarlane, Lee et al. 2006; Troiano, Berrigan et al. 2008). In people with chronic obstructive pulmonary disease (COPD) a lower average (13.1) hours/day wear time was reported over a 3-day time period (Steele, Holt et al. 2000). A recent study reported an average of 11 hours/day with the RT3 monitor over two periods of seven days in patients with a mixture of neurological disorders (Hale, Pal et al. 2008). The lower average hours/day wear time may arise from increased hours of rest due to the underlying health condition. However, few studies have reported on actual wear hours or the change in wear hours in a repeated measurement design.

Data loss due to battery connection faults in the final week of data gathering caused 45.2% of the total data loss, and accounted for 93.3% of the activity monitor related factors for data loss. This complete loss of a week's data is a potentially serious utility concern, as it necessitates statistical manipulation on the non-complete data to minimise group effects (Catellier, Hannan et al. 2005). A similar percentage loss of participants' data loss (10%) was found with the RT3 in a LBP population (10%) (Verbunt, Sieben et al. 2005), and Sloane et al (2009) reported that 13% (15/115) of participants' RT3 data at baseline was unusable in a cohort of cancer survivors. It is likely that the rate of technical failure in the current study was related to the number of repeat measures and the number of monitors used (8), relative to the number of participants (21), as well as specific monitor design limitations. It also appears that the population under study may potentially have less utility issues than a more disabled population.

Most participants reported that the RT3 was acceptable to wear, application was easy to remember, and did not interfere with daily activities. However, forgetting to wear the RT3 increased over the three repeated weeks, and was responsible for an estimated 169.5 hours (38.2%) of total RT3 data loss, and was the primary cause of participant related data loss (74.2%). Forgetting to wear the monitor has been reported extensively in the literature (Kochersberger, McConnell et al. 1996; Steele, Belza et al. 2003). Conn et al. 2000 found that 28% of participants (average age 74 years) did not complete a full complement of seven to nine days of data collection due to both RT3 malfunction and forgetfulness in wearing the

monitor. In the current study placement site and bulk of the RT3 was most problematic for participants in sedentary occupations. Five participants removed the monitor during more manual aspects of their job or studies. Removal of the monitor during work time accounted for a relatively small percentage of data loss in sedentary occupations; however, this factor could potentially result in an underestimation of participant physical inactivity within these occupational groups.

There was decreased adherence to monitor wear over time. Research suggests a variety of frequent cues and incentive payments to increase participant adherence (Trost, McIver et al. 2005; Van Coevering, Harnack et al. 2005). Although no incentive payment was provided, a reminder was delivered twice via the participant's stated preferred method of communication. The additional use of an activity diary was beneficial to not only provide more detail of daily activity, but also to act as a cross reference to the activity monitor output to enable an accurate estimation of potential data loss (Buchheit, Platat et al. 2007), and as a prompt to wear the activity monitor.

Results from the utility questionnaire highlighted that sitting or driving with the monitor placed on the central lumbar spine was uncomfortable and when in prolonged sitting. Also the monitor caught under the backrest of chairs and participants frequently reported that the monitor was knocked off during sit to stand activities. These occurrences resulted in a fear of losing the RT3 which accounted for seven hours of data loss. An earlier study previously explored various psychometric properties of the RT3 in patients with neurological disease, and also found major themes of discomfort and fear of losing the monitor (Hale, Pal et al. 2008). These results may not have occurred if the monitor had been placed on the belt line or waist band over the lateral pelvis. This study determined that placement in the centre of the lower back would potentially not be acceptable for those complaining of lower back pain, and for those in occupations which require high periods of time spent sitting. While data loss due to activity participation is important to recognise, the majority of non-recorded activity hours in this current study was not linked to participation in a particular sporting or occupational activity.

5.5.2 Number of days of activity measurement required

Previous research using a variety of outcome measures has reported a range of recording days (5 - 28) as required to reliably measure PA in healthy, free-living adults (Coleman and Epstein 1998; Baranowski, Smith et al. 1999; Trost, Pate et al. 2000; Matthews, Hebert et al.

2001). Reliability is a function of between-subject variance in activity, and individual daily fluctuations (within-subject variance). Despite the relatively young and healthy population, where a large variation in activity should be expected, mean PA levels were reasonably stable over the three recording weeks. However, a high variability in PA within a week was found, which may be due to chance, and also because weekend days were sampled together with weekdays and analysed separately. If only weekday data were sampled, fewer days of sampling would be required to give an estimate of activity, due to the lower within subject variability observed on these days. This would mean only a modest elevation of sample size requirement for future prospective powered research compared to sampling a seven day mean. Some authors have suggested that there is no practical difference between the days of the week that are chosen when estimating weekly PA (Tudor-Locke, Burkett et al. 2005), while others have proposed that it is unrealistic to assume equal covariance of activity between days (Baranowski, Smith et al. 1999) due to the difference in activity between weekend and weekday data. Results of the present study support previous research; that inclusion of at least one weekend day in activity measurement is required due to the greater variability between weekend and week day activity (Metzger, Catellier et al. 2008).

Data from week two illustrated a paradoxical phenomenon, in that the seven day mean was not variable, but samples taken from within particular seven day durations of measurement were found to be highly variable. The increased intra-individual variability within this week may be due to days with high activity within one week then being accompanied by days with low activity in the same week, and these differences masked by taking combined means. Results from this study show that the choice of number of days required to give an accurate estimate of the variance in activity is dependent upon the day-to-day variability of the population cohort under study. Importantly, while the total amount of variance in PA as measured by the RT3 was lower for seven days when compared to four days of data collection, there was no appreciable change in the ratio of variance estimates by including more than four days of data collection in weeks 1 and 3, suggesting that at least four days of data collection (including one weekend day) provided a relatively reliable and accurate representation of each participant's activity levels. The potential relevance of which specific weekdays are chosen for monitoring requires further exploration, as daily variability in activity is probably dependent on the population.

Results found that the RT3 demonstrated good utility within this healthy population over the three repeat measurements. Data loss was not a significant problem over the three weeks of

data collection; although loss of data did increase over the measurement periods, it did not negatively affect the variance estimates in PA measurement. Issues of monitor placement, adherence, and technical factors (particularly loss of battery contact) were identified as the main issues for further consideration in a larger prospective trial.

The relatively small number of participants in the current study (n = 21) means that the reported reliability and variance models need to be validated in larger prospective trials, with a wider selection of both age and occupational groups. However, results from this study will be useful for power and sample size calculations for prospective research on the measurement of activity over time for the RT3.

5.6 Conclusions

Results of this study identified a number of key issues, important for the design of the longitudinal study measuring PA with the RT3. High levels of intra-individual variance in PA were seen in healthy individuals measured with an RT3, and although participants' activity levels remained fairly consistent over the three weeks of monitoring, both day and week contributed approximately one third of the variance in activity. Variance in PA was found to be greater at weekends and particularly marked on a Sunday, supporting the requirement for at least one weekend day in activity measurement. Four days of measurement including one weekend day collected over a seven day period would be sufficient to give an accurate estimation of PA for this healthy population over the three repeat weeks.

The RT3 was acceptable to wear, and data loss did not appear be a significant factor in affecting the variance in PA over the three recorded weeks of measurement. Missing data were equally due to both monitor and participant factors, both require consideration for prospective longitudinal studies. The RT3 demonstrated good utility and the hours of wear remained high over the three measurement periods. The results however, emphasised the need to develop effective protocols to maintain adherence to wear time in longitudinal research.

The following chapter outlines the methodology to assess activity levels in free living of an acute LBP population, using an RT3 in a longitudinal design in order to investigate the predictive associations to LBP outcomes.

CHAPTER VI

An outline of main study methods to investigate predictive associations between activity and LBP outcomes

6 Methods of main study to investigate predictive associations between activity and LBP outcomes

6.1 Introduction

The systematic review revealed no published studies have objectively assessed activity levels within an acute LBP population to determine changes over time, and or whether such change predicts recovery. The aim of this study was to determine whether an objective measure of change in PA predicts recovery in a cohort of acute LBP.

6.1.1 Research objectives

In a cohort of acute LBP patients (< 6 weeks' duration) (Grotle, Brox et al. 2004).

1. Determine whether change in objectively measured levels of PA predicts change in functional outcome at 3 months and at 1 year
2. Assess the effect of occupation and occupational activity levels, personal factors, pain levels, functional status, and psychosocial profile on the association between PA levels and LBP outcomes at 3 months and at 1 year.
3. Determine the association between restoration of "normal" levels of PA (from self-report by the patient) and functional disability (RMDQ).

- **Hypotheses**

Three specific hypotheses will be tested:

1. Baseline PA levels of participants with acute LBP and change in PA from baseline to 3 months are a positive predictor of recovery at 3 months and at 1 year;
2. Psychosocial factors confound the observed association between activity change and the course of LBP at 3 months and over a 1 year period;
3. Restoration of "normal" levels of PA at baseline and at 3 months is a positive predictor of functional disability over a 1 year period.

6.1.2 Study design and participant recruitment

A prospective cohort study recruited patients by public advertising: this included local newspapers, public notice boards, posters, and mail-outs to local physiotherapy clinics in the urban and sub-urban environment in Dunedin, New Zealand. In addition, participants were recruited via email notification of university staff and students at the University of Otago,

Dunedin. All participants interested in the study were encouraged to contact the principal investigator (PI) via telephone or e-mail to undergo initial screening for inclusion into the study. Recruitment took place over a one year period (March 2007 to March 2008). The study protocol was approved by the Lower South Regional Ethics Committee (LRS/07/11/043) (Appendix pages 209-218), and the Ngāi Tahu Research Committee provided feedback when consulted regarding Maöri consultation (Appendix page 208).

6.1.2.1 Inclusion and exclusion criteria

To be eligible, participants fulfilled the following criteria:

- An episode of LBP of 6 weeks or less proceeded by at least 3 months of freedom from LBP symptoms. These inclusion criteria excluded the chronic LBP population (defined as symptoms exceeding 3 months) (Van Tulder et al., 2006).
- Between the ages of 18 and 65 years (working age population).
- English speaking and able to provide informed consent to PA monitoring and follow up for 12 weeks. This was to ensure that all participants could complete the questionnaires.
- No other pre-existing clinical conditions which limited mobility or PA levels.
- Receiving physiotherapy treatment for the current episode of acute LBP. This inclusion criterion was applied to specifically study the population that attends for physiotherapy i.e. that had reached a threshold where they seek clinical intervention. This threshold was set to focus the research and generalisability of the research findings to this specific population.
- Achieve a minimal score of 4 on the RMDQ. This score allowed for the detection of the smallest clinically important change in this measurement (Van Tulder, Becker et al. 2006). This threshold was chosen based upon the estimated mean baseline RMDQ score (10 to 14) (Stratford, Binkley et al. 1998; Kovacs, Abraira et al. 2007). Taking into account that a 30% change threshold score has recently been proposed as a meaningful change score for the RMDQ (Ostelo, Deyo et al. 2008), the threshold for the minimal change in RMDQ was set at 4.

The following criteria were investigated at an initial screening interview by the PI prior to recruitment and used to exclude participants. Serious or systemic spinal pathologies including persistent or progressive neurological deficit, intractable pain, spinal surgery, or symptoms of inflammatory disorders as assessed and reported by their health practitioner or identified by screening questions from the co–investigator. Any history of current or past medical problems

(other than LBP) which prevented participants from undertaking usual day-to-day activities precluded participation in the study (Appendix page 226).

6.1.3 Sample size and statistical power

The sample size was calculated for 80% power at a two-sided type I error rate of 0.05, assuming a standard deviation of change in RMDQ score of 5.4 over a 3 month period, (Riddle, Stratford et al. 1998; Stratford, Binkley et al. 1998) and the detection of a clinically meaningful change of 4 points in the RMDQ score from week 1 to week 12 (Ostelo and de Vet 2005; Van Tulder, Becker et al. 2006). The sample size was then adjusted based upon the detection of a difference in change in RMDQ from baseline to three months in two groups classified as 1) those who had a high change in PA from baseline to 3 months and 2) those who had low or no change in PA from baseline to 3 months. High change in PA was defined by the upper quartile of change in PA from baseline to 3 months. Assuming unequal group sizes between those with a high change in PA levels versus low change in PA levels required a sample size of 65 participants. Previous research employing the RT3 in free living had found loss of data due to technical issues including monitor malfunction to be a significant issue (Bousema, Verbunt et al. 2007; Matton, Wijndaele et al. 2007). Therefore a reasonably high attrition rate was predicted with a potential dropout rate of 40 to 50% over the three time points. Thus data were required from approximately 100 to120 participants in order to reach the predicted sample size.

6.1.4 Pre monitor testing

All RT3 monitors underwent testing prior to field use as part of the standardised protocol recommended when employing accelerometry measurement (Ward, Evenson et al. 2005). It is recommended that intermonitor variability and reliability of RT3 along each axis be tested prior to field use (Powell and Rowlands 2004). To evaluate the technical performance of the nine RT3 accelerometers in this study for field use, each monitor was subjected to a specific vibration testing along each sensitive axis in isolation. A motorised vibration table was used (RM2 Reciprocating Mixer, Ratek Instruments Pty. Ltd) that was set to produce a frequency of 3.3Hz. Thus the acceleration for the RT3 testing was conducted at 200 shakes/minute with a displacement of 33mm (measured with Mitutoyo Digimax Callipers CD-8” CX) which produced an acceleration force of 0.74g (see derivation of calculation below).

The motion comes from a circular motor translated into horizontal motion so the motion is sinusoidal. d (t) =D sin (wt) where d (t) is displacement with time: D is maximum displacement (about a centre point), w is angular velocity (1 Hz = 2pi radians per second). f is frequency of oscillation (in Hertz) ω is angular velocity. ω = 2πf (in Radians per Second) D is the maximum distance from a central point (in metres). I.E. half the maximum travel. We know from the mechanical construction that distance, d, varies with time, t, in a sinusoidal manner.

$d(t) = D \sin(\omega t)$

To get the velocity formula, v(t), we need to differentiate the distance formula.

$v(t) = d'(t) = D\omega \cos(\omega t)$

To get the acceleration formula, a(t), we need to differentiate the velocity formula.

$a(t) = v'(t) = -D\omega^2 \sin(\omega t)$

The maximum magnitude of acceleration, A, occurs when the sine function has the value 1 or -1. Since we are interested in magnitude not direction the sign is irrelevant.

$A = D\omega^2 = D(2\pi f)^2$

Calculation of g force on shaker table

f=3.3 (200 shakes per minute/60)

ω=21 (Rotational frequency)

D=.0165m (.033/2 from measurement)

$A=7.3 m/s^2$

A =0.74g

Each monitor was placed in turn on the X, Y, and Z axis, secured within a box on the table, and tested for 5 minutes. This procedure was repeated six times on each axis (further results presented in Appendix pages 219-221). Data were analysed for axis effects, and inter- and intra-instrument variability. Differences in RT3 output for each axis were explored using two-way repeated measures (ANOVA) by accelerometer (9) and by axes (3). Significance level was set at $p< 0.05$, and all analyses used SPSS software version 14.0 (SPSS Inc., Chicago, Ill).

Analyses showed a main effect for RT3, $F (8, 40) = 311.9$, ($p < 0.0001$), vector axis, $F (2, 10) = 7.3$, ($p = 0.01$), and an RT3 and axis interaction, $F (16, 80) = 211.7$, ($p < 0.0001$). There was greater inter-instrument CV and SEM on the Z axis (CV = 35.7, SEM = 93.1) compared to the X (CV = 10.8, SEM = 64.9) and Y (CV = 14.2, SEM = 32.5) axes respectively (Table 6-1).

Inter instrument CV across all monitors on each of the 3 axes ranged from 10.8 to 35.7 (Table 6-1). The intra class correlation (ICC) for intra axis reliability for the RT3s ranged from 0.98 to 0.99.

Table 6-1 Descriptive statistics of RT3 output by axes for the 9 monitors tested

Axes	Mean VM/min	SEM	95% Cl	Std. Deviation (SD)	Inter monitor CV
X	12305.8	64.8	12175.2 - 12436.5	1336.2	10.8
Y	12603.5	32.4	12538.1 - 12668.9	1794.5	14.2
Z	12862.1	93.0	12674.7 - 13049.6	4589.4	35.7

There was a significant difference in the counts recorded on the X, Y, and Z axes at 3.3 Hz; whereby the counts recorded along the Z axis were significantly higher than the counts on the X and Y axes (Figure 6-1). These findings are similar to previous studies which have also shown reasonably high levels of RT3 intra-monitor reliability, and more variable axis-dependent inter-monitor reliability on a shaker table (Powell, Jones et al. 2003; Krasnoff, Kohn et al. 2008). As a result of testing, 8 monitors were considered to have high levels of intra- monitor reliability for field use (ICC = 0.99), while one monitor with larger variability on the Z axis was sent for re-calibration (StayHealthy, Inc., Monrovia, California) before field use.

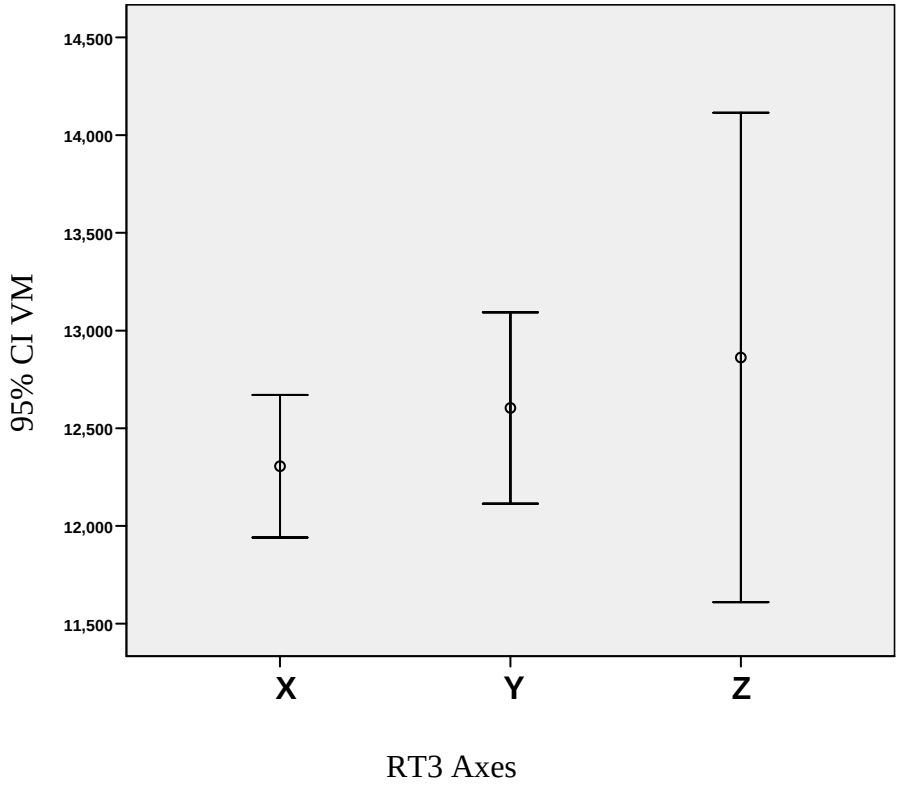

Figure 6-1 95% CI for RT3 output by axes across trials

6.1.5 Procedures

The screening questionnaire referred to above was adapted from the New Zealand Accident Compensation Corporation (ACC) guidelines (ACC. 2004, part 1, pages 8-10) (Appendix page 226) and is designed to detect potentially significant symptoms of serious spinal pathology. Evidence for such a disorder excluded participants from the study.

At an initial visit, each participant's weight (Seca Alpha Model 170), height (stadiometer, Seca 214, portable), age, sex, occupation, and ethnicity were recorded. Participant's height and weight were used to calculate body mass index (BMI) (mass (kg)/height2 (m2). Coding of their occupation was carried out according to Australian and New Zealand Standard Classification of Occupations to allow for inclusion as a potential confounder in the analyses (Australian, Bureau et al. 2005).

The main occupation was recorded and divided into predominantly manual (involving manual lifting, heavy labour, or regular bouts of physical activity or exertion) or non-manual. The PI also recorded whether the participant was working or off-work due to the current LBP

episode, the number of days of the week, and total average hours that each participant worked, and whether the participant considered their work to be either manual or sedentary (Appendix pages 227-228).

The specific details for each participant (name, age, height, weight and sex) were input into the RT3 monitor and the monitor was worn in a clip-on holder attached to the hip. Placement of the RT3 was demonstrated by the PI and practised by each participant. Participants were asked to wear the RT3 monitor on the right hip for all waking hours; except for water-based activities or sports activities (such as rugby) which precluded the use of an activity monitor. If the monitor caused discomfort in this position, participants were advised to shift it to the lateral right pelvis to note the change of position in the activity diary, and to return the monitor to its original position when appropriate. Participants were advised that the monitor should be placed in a prominent and clearly observable position overnight to avoid the participant forgetting to wear it the next morning. They were also asked to report wear times and reason for removal and to note the days that they work; also to report sleep patterns (Ward, Evenson et al. 2005), and hourly activities in an activity diary (Appendix pages 229-232) over the week, and were also asked to record their sleep times and to note removal of RT3 and reasons for such removal (Hale, Pal et al. 2008). These self-report data were used to confirm unusual patterns of activity observed in the RT3 data, and also provided a cue for participants completing the 7D-PAR questionnaire.

The RT3 monitors were set to mode 4 for this study, which stored and calculated an accumulated activity count (VM count) for each one-minute epoch over the 7 days of monitoring. Although the RT3 demonstrates high levels of intra-monitor reliability (Powell and Rowlands, 2004, Krasnoff et al., 2008) inter- monitor variability is known to be more variable (Powell, Jones et al. 2003; Krasnoff, Kohn et al. 2008) and therefore each participant used the same monitor for the repeat testing measurement (Chen, Jerome et al. 2009).

6.1.6 Outcome measures

Participants completed a number of validated LBP outcome measures at baseline and at 3 months and at 1-year. Each of the questionnaires was completed in the presence of the PI at baseline (at the home of physiotherapy clinic of the participant) to improve compliance and checked for completeness at the end of the session. The participant completed the RMDQ questionnaire, comprising of 24 items which refers to limitations of daily activities as a result of the current episode of acute LBP. Participants also completed the VAS for pain scaled from

0 to 10 in which the participant was asked to rate the level of pain at its worst over the past 7 days (Appendix page 235). A specific activity questionnaire developed for this study asked participants whether they had returned to full “normal” activities (Yes or No) since the episode of LBP (Appendix page 233).

6.1.7 Measurement of low back pain specific domains

Participants completed the BPAQ (Appendix page 234), FABQ (Appendix page 236) and the GHQ-12 questionnaires (Appendix page 242-243) to measure for potential confounding factors (Table 6-2): The BPAQ questionnaire assessed habitual activity levels prior to the onset of the current episode of LBP it is divided into three sections (work, sports and leisure), worded such that participants are asked about activity levels over the previous year prior to the onset of LBP. The FABQ questionnaire consists of two subscales: fear-avoidance beliefs about work (FAB-work), and fear-avoidance beliefs about physical activity (FAB-physical activity). The GHQ12 questionnaire consists of 12 items rated on a four-point scale (less than usual, no more than usual, rather more than usual, or much more than usual), and uses a Likert scale (0-1-2-3) giving a total score ranging from 0 to 36.

The PI contacted participants twice by text and or telephone to enhance compliance with wearing the RT3 and to address any problems they might be having with either the RT3 or the activity diary. At the completion of the week, the PI met with the participant to collect the RT3 and the activity diary. The activity diary was checked by the PI for completeness and any missing data were added at this point after consultation with the participant. RT3 data were downloaded to a portable computer.

Each participant completed the 7D-PAR (Appendix page 244) (Bonnefoy, Normand et al. 2001). Prior to completion of the 7D-PAR, participants were instructed that “normal walking” and its equivalent represented moderate activity; vigorous housework and heavy manual labour were the equivalent of hard work; and running was classified as very hard. The amount of time, in minimum 10 minute epochs, spent in light, moderate, hard, and very hard activities during each recorded hour of the day was then recorded for the seven days that the monitor was worn (Sarkin, Campbell et al. 1997). Participant’s daily activity log recorded their primary activities for each hour and their waking and sleeping times, and was employed as a cue and prompts to aid recall of other activities which had previously not been mentioned.

6.1.7.1 Three month measurements

All participants were sent a reminder letter of the second monitoring time between the first and second period of monitoring (Appendix page 245), contact was made approximately one week prior to their scheduled date for re-monitoring at the 3-month point, to further remind and encourage participants to continue in the study. Each participant then repeated the RT3 activity monitoring procedure described at baseline and also completed the RMDQ, VAS and simple activity questionnaire at this time point.

At the completion of the week of monitoring, the PI arranged to meet with the participant to download RT3 data, administer the 7D-PAR and collect the activity diary. In addition the participant completed an RT3 utility questionnaire developed for this study (Appendix pages 240-241). This questionnaire was designed to assess any specific utility issues of PA measurement using the RT3 at the two measurement points.

6.1.7.2 One year measurements

At 12 months the following questionnaires were posted (plus return envelope) to each participant for completion: VAS, RMDQ, the BPAQ, and a modified Nordic LBP Questionnaire (Hartvigsen, Frederiksen et al. 2006). The BPAQ is worded to record habitual levels of PA over the one year duration since the episode of LBP (table 6-2). Participants returned the questionnaires by post and were telephoned and sent a further reminder letter if no reply was received after three weeks. Figure 6-2 shows a timeline for recruitment, data collection, and completion to the 3 month point. The full duration of the study was approximately two years to complete recruitment and one year to follow-up all participants.

Table 6-2 Measurement outline at each time point

Time Point	Activity Measurement	Low Back Pain Measurement	Other Measures
Baseline All measurements collected under PI supervision	BPAQ, 7D-PAR, Activity diary, RT3 (worn for 7 days), Specific Activity Questionnaire	RMDQ , VAS	FABQ, GHQ-12
3 months All measurements collected under PI supervision	BPAQ, 7D-PAR, Activity diary, RT3 (worn for 7 days), Specific Activity Questionnaire	RMDQ, VAS	FABQ, GHQ-12
1 year All measurements self-administered by postal questionnaire	BPAQ, Specific Activity Questionnaire	RMDQ, VAS and Nordic LBP Questionnaire	

7 D-PAR; Seven Day Recall Questionnaires, BPAQ; Baecke Physical Activity Questionnaire; FABQ; Fear-Avoidance Beliefs Questionnaire; GHQ12; General Health Questionnaire; RMDQ; 24-item Roland Morris Disability Questionnaire; VAS; Pain Visual Analogue Scale

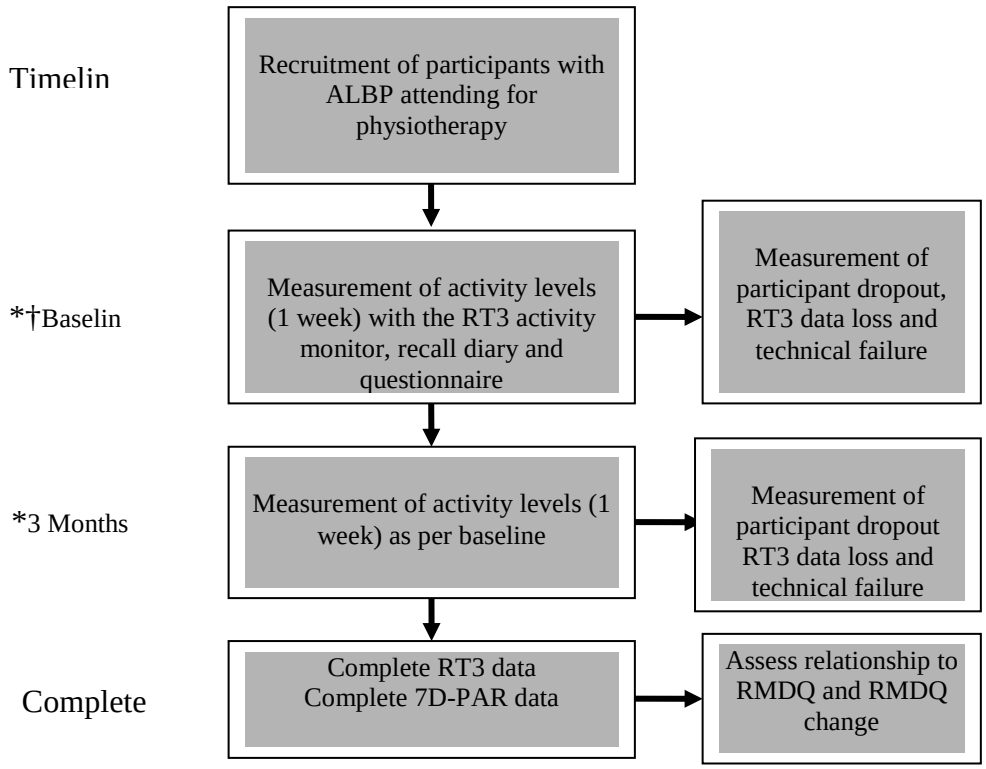

Figure 6-2 Physical activity monitoring flowchart

*At each time point data on low back pain and functional disability (RMDQ) was collected

† At baseline data on occupational, psychological and behavioural factors collected

6.2 Analyses

6.2.1 Data management

Following collection, RT3 data were checked for accuracy and completeness. In order to be included in the analysis, each participant was required to have a minimum of 10 hours of RT3 data on five or more days of the week, including one weekend day (Gretebeck and Montoye 1992). This process involved downloading all accelerometry data via StayHealthy^{tm} software into an Excel database. An initial visual review of all accelerometer data was then undertaken to determine the number of days of accelerometer data recorded, and to also determine whether the data satisfied the research protocol criteria for inclusion.

The downloaded accelerometry data were then re-checked to ensure that the number of days of accelerometer data matched the protocol, to ascertain sleep times, RT3 removal, and to identify possible RT3 malfunctions (Alhassan, Sirard et al. 2008). Data were then scanned for non-worn periods, and wear time was determined by subtracting non-wear time from 24 hours. Non-wear was defined by an interval of at least 60 consecutive minutes of zero activity intensity counts, with allowance for 1-2 minutes of counts between 0 and 100 (Troiano, Berrigan et al. 2008). Such data were deemed to be 'missing' (Ward, Evenson et al. 2005). For the analysis presented here, a valid day was defined as having 10 or more hours of monitor wear. Estimates of data loss and the reasons for any activity data loss was also investigated (Paul, Kramer et al. 2008). Hours of sleep, as recorded in the activity diary, were not considered to be activity data, and were therefore not included in any missing data analyses. The management of missing data was dependant upon the amount and type of data loss encountered as it is recognised that mixed models analyses give unbiased and consistent estimates when the data are missing completely at random.

The score from the RMDQ questionnaire was calculated by adding the number of questions which had been ticked or marked by each participant, and the data stored in Excel. A record of the participant's numerical rating of pain along the scale line was taken and a recorded measurement of the distance (from 0) of the mark placed on the VAS line was used if no numerical value was given. The participant's response to a return to full 'normal' activities (Y/N) was also recorded and coded. Scores for the responses for each of the questions within the three sections of the BPAQ were entered for these three sections (work, sports and leisure) and calculated in Excel^{TM} as indicated (Baecke, Burema et al. 1982).

Scores from each of the responses from the FABQ and calculation of the FAB-work score was undertaken in Excel as the sum from items 6, 7,9,10,11,12 and 15 giving a maximum scale score of 42 (7 items). The FAB-physical activity was calculated as the points summed from items 2, 3, 4 and 5, giving a maximum score of 24 (4 items) Waddell, Newton et al. 1993). Responses and scores from the GHQ12 were entered to give a total score which ranged from 0 to 36. Responses from the Nordic questionnaire at 1 year were coded and entered into Excel^{TM}.

6.2.2 Data analyses

Data were separated into weekdays and weekend days. The sum of RT3 activity counts for each day was calculated, as well as the total number of hours of activity data collected each day. Total weekly RT3 activity counts were divided by the total number of hours worn from each valid day of data collection (Alhassan, Sirard et al. 2008). Descriptive statistics including mean, range, and SD were presented for the main PA outcome variables. The amount of physical activity as measured by the RT3 accelerometer was presented in two ways: 1) mean daily VM counts (VM/day), 2) mean VM counts per hour (VM/hr/wk).

Change in RT3 activity was calculated as VM/hr/wk at 3 months minus VM/hr/wk at baseline. The standard deviation of RT3 VM/hr/wk was calculated at the two time points as a measure of variability in PA. Data were collected at 3 months, irrespective of whether complete RT3 data had been collected at baseline. However, only those with complete RT3 data at both time points were used in the investigation of RT3 activity change and RMDQ change. Change score for RMDQ was calculated by subtracting each participant's 3 month RMDQ score from their baseline RMDQ score.

Daily PAEE from the 7D-PAR (kcal/kg/day) was calculated as the average number of hours in each activity multiplied by the MET value assigned to the activity category (light = 1.5, moderate = 4, hard = 6, very hard = 10). Change in PAEE was calculated as the average daily PAEE at 3 months minus average daily PAEE at baseline. The distribution of data was checked graphically before parametric analyses were employed. Two sample t-tests and Pearson correlations analysed the difference and the association between the groups of parametric scale variables respectively. Comparisons of the binary variable "returned to normal activities" (Yes/No) at the two time points were made using McNemar's test.

Simple linear regression was used to assess the unadjusted association between the RMDQ change and RMDQ score at 3 months and the main predictor variables of interest: levels of activity change with the RT3 and 7D-PAR from baseline to 3 months. Unadjusted linear regression also included the following co-variates as possible confounders; age, sex, occupation, BMI, baseline levels of pain, functional status, depression, anxiety, emotional distress and fear avoidance (GHQ12 and FABQ), and activity levels prior to the onset of LBP (Baecke work, sport and leisure scores), as well as measures of activity levels at baseline measured with the RT3 and 7D-PAR.

Two adjusted analyses were performed. The first adjusted for all variables whose p-value was < 0.1 in the unadjusted analyses. The second began with these variables and performed a backwards selection multiple linear regression model, which forced change in PAEE to be included. For those variables which remained in the final model, an examination of their significance ($p< 0.05$) was undertaken to evaluate their contribution to the final model.

At 1 year, two sample t-tests and Pearson correlations analysed the difference and the association between the BPAQ change score from baseline (pre-LBP) to BPAQ score at 1 year (ΔBPAQ). Logistic regression investigated the association between: (1) measures of activity prior to onset of LBP (Baecke work, leisure and sports scores), (2) measures activity levels at baseline and 3 months (RT3 and 7D-PAR), (3) change in activity from baseline to 3 months (change in RT3 VM counts/hour/week from baseline to 3 months), and presence or absence of on-going low back pain (Y/N) from the modified Nordic LBP questionnaire. Included in the model were the following variables: age, sex, occupation, baseline and 3 month pain levels (VAS scores), functional status (baseline and 3 month RMDQ) and baseline measurements of depression, anxiety, emotional distress and fear avoidance (GHQ12 and FABQ). Activity levels prior to the onset of LBP and over the year period since the episode of LBP were also included in the model. (BPAQ scores at baseline and 1 year).

Simple linear regression was used to assess the unadjusted association between ΔRMDQ from baseline to 1 year and the main explanatory PA variables of interest (as outlined above). Unadjusted linear regression also included the following variables; age, sex, occupation, BMI, baseline and 3 month levels of pain, RMDQ, baseline levels of depression, anxiety, emotional distress and fear avoidance (GHQ12 and FABQ) and activity levels prior to the onset of LBP and over the previous 1 year (BPAQ scores at baseline and 1 year) as well as measures of activity levels at baseline and 3 months measured with the RT3 and 7D-PAR.

Two types of adjusted analyses were carried out. The first adjusted for all variables whose p-value was < 0.1 in the unadjusted analyses. For those variables which remained in the final model, an examination of their significance ($p< 0.05$) was undertaken to evaluate their contribution to the final model. All analyses used SPSS software version 14.0 (SPSS Inc., Chicago, Ill).

CHAPTER VII

Main study to investigate predictive associations between activity and LBP outcomes: Results

7 Results of main study to investigate predictive associations between activity and LBP outcomes

7.1 Baseline and 3 month results

One hundred and one participants were recruited, of whom 83 completed the study at the three month point.

7.1.1 Demographic and baseline results

Eighty six percent of the recruited patient population identified themselves as NZ European, while 8% identified as Maori or Pacific Island ethnicity. Table 7-1 shows the demographic features of the recruited patient population (n =101). Of the 67 workers, only five reported being currently off work due to their LBP.

Table 7-1 Baseline demographic measurements

Baseline descriptive statistics (N = 101)	Mean (SD)
Age (years)	37.8 (14.6)
BMI	26.2 (4.8)
	N (%)
Female	51 (50.5)
Male	50 (49.5)
Non-manual occupation	24 (23.8)
Manual occupation	44 (43.6)
Student	25 (24.8)
Not working	8 (7.8)

Table 7-2 presents baseline fear avoidance, anxiety, and depression scores (GHQ12) scores, as well as self-reported PA levels prior to the onset of LBP.

Table 7-2 Baseline measures of fear avoidance, activity and psychological distress

Baseline Measures	Range	Mean (SD)
FABQPA	0 to 24	14.6 (5.4)
FABQ W	0 to 42	15.8 (9.4)
Baecke Work Index	1.4 to 4.1	2.8 (0.7)
Baecke Sport index	0.8 to 5.8	2.6 (1.2)
Baecke Leisure Time Index	1.8 to 4.5	2.9 (0.6)
GHQ12	4 to 23	11.9 (4.2)

FABQPA: Fear avoidance belief questionnaire;

GHQ12: General Health Questionnaire

7.1.2 Data sets

Table 7-3 shows RT3 utility measurements at baseline and at 3 months. Ninety two participants had complete data at baseline, 85 had complete data at 3 months, with two of these having incomplete data at baseline, resulting in 83 participants with complete data at the two time points.

Table 7-3 Utility issues of measurement of activity with the RT3 and 7D-PAR

	Baseline (n =101)	3 months (n = 90)
Participant dropout	3	8
RT3 technical failure	4	2
RT3 participant loss	2	1
Number of lost or incomplete days of RT3 data collection (%)	84/^{ð}686 (12.2%)	91/ ^{γ}630 (14.4%)
**No of days with RT3 data > 10 hours (%)	602/ ^{ð}686 (87.7%)	539/ ^{γ}630 (85.6%)
No of participants with 5 days of greater than 10 hours RT3 wear/day	92	85
Wear hours/day Mean (SD)	13.4 (1.9)	13.5 (1.9)
7D-PAR data	98	90

**complete data = 10hours/day on at least 5 days (including 1 w/e day)

ð = 98 X 7 possible days of data collection, γ = 90 X 7 possible days of data collection

Reasons for incomplete RT3 data were participant drop out at baseline (n = 3), and at 3 months (n = 8), RT3 technical issues at baseline (n = 4) and 3 months (n = 2), and RT3 loss by the participant at baseline (n = 2) and 3 months (n = 1). Estimated number of days of lost

data at baseline (12%) and 3 months (14%) were comparable, as were mean device usage hours/day. Ninety participants had complete 7D-PAR data at 3 months. Reasons for non-completion of 7D-PAR data (n = 11) were primarily due to participant drop out at either baseline (n = 3) or at 3 months (n = 8). The percentage of days on which RT3 data were collected exceeded the minimum requirement for inclusion into the study at both baseline (88%) and 3 months (86%) (Chapter V). The average daily wear times were also very similar at these two time points.

7.1.3 Results of LBP outcome measures

Table 7-4 presents the baseline measures and main LBP outcome measures at 3 months. Baseline measures show moderate levels of disability, with a significant percentage reporting that they had not returned to "normal" activities. At 3 months there was a statistically significant improvement in both the primary and secondary outcome measures (i.e. RMDQ for function and VAS for pain).

Table 7-4 Results for primary and secondary outcome measures: Comparison of baseline and 3 month pain and functional outcomes

	Baseline Mean (SD) (n = 101)	3 months Mean (SD) (n = 90)	Mean Difference (95% CI)	t-tests P value
RMDQ score	8.1 (3.8)	1.7 (2.9)	6.1 (5.2 to 7.1)	p < .0001
VAS score	57.4 (19.7)	15.2 (19.6)	42.8 (37.4 to 8.2)	p < .0001
	N (%)	N (%)		McNemar's test P value
Return to normal activities	23 (22.8)	69 (76.4)		p < .0001

RMDQ Roland Morris Disability Questionnaire; VAS Visual Analogue Scale

7.1.4 Physical activity results

Measures of PA collected with the RT3 at baseline and 3 months are shown in Table 7-5 for all participants, and for those with complete data at the two time points.

Table 7-5 Results for RT3 activity monitoring: Comparison of RT3 VM data at baseline and 3 months

	Baseline Mean (SD) (n = 92)	3 months Mean (SD) (n = 85)
RT3 mean VM/day	337228.2 (204476.3)	344331.5 (209527.4)
RT3 VM/hr/wk	25166.6 (10905.7)	25229.3 (12295.9)
**RT3 VM/hr/wk	24871.6 (11117)	25410.3 (12387)

**Complete data at baseline and 3 months (n = 83)

The RT3 VM/day and VM/hr/week at baseline and 3 months for those with complete data sets (n = 83) and for the 90 participants with complete data from the 7D-PAR are presented in Table 7-6.

Table 7-6 Comparison of physical activity measures at baseline and 3 months

	Baseline data Mean (SD)	3 month data Mean (SD)	Mean Difference (95% CI)	t-tests P value
RT3 VM/hr/wk (n = 83)	24871.6 (11117.7)	25410.3 (12387.9)	538.7 (-2399.6)- 1322.1)	0.566
Daily PAEE kcals/kg (7D-PAR) (n = 90)	14.5 (5.7)	15.1 (7.3)	0.6 (-1.8 to 0.7)	0.383
Moderate hours of activity/day (n = 90)	1.6 (1.2)	1.5 (1.7)	0.1 (-0.3 to 0.5)	0.516
Hard hours of activity/day (n = 90)	0.4 (1.0)	0.5 (1.1)	0.1 (-0.2 to 0.1)	0.552
Very hard hours of activity/day (n = 90)	0.1 (0.2)	0.1 (1.7)	0.06 (-0.06 to 0.02)	0.241

Paired t-tests showed there were no statistically significant differences from baseline to 3 months in (1) the activity levels recorded with either the RT3 or the 7D-PAR; or (2) the amount of hours recorded as moderate, hard, or very hard from the 7D-PAR. The only difference in baseline measure noted between those lost to follow-up and those with complete data was a greater percentage of those with complete RT3 data having not returned to full normal activities at baseline (Table 7-7).

Table 7-7 Comparison of those with complete RT3 data against those lost to follow-up at 3 months: comparing main dependent variables and outcome measures

	Incomplete RT3 data (n = 18) Mean (SD)	Complete RT3 data (n = 83) Mean (SD)	Paired t-test P values
Baseline PAEE kcals/kg	113.3 (60.3)	100.4 (40.7)	0.12
Age (years)	33.2 (15.6)	38.8 (14.4)	0.74
BMI %	26.6 (4.7)	26.0 (4.8)	0.80
Baseline RMDQ score	7.5 (3.11)	8.2 (3.9)	0.15
Baseline VAS score	50.1 (21.53)	58.9 (19.2)	0.44
FABQPA	15.2 (5.5)	14.4 (5.5)	0.79
FABQW	17.7 (8.3)	15.3 (9.6)	0.15
Baecke Work Index	2.9 (0.8)	2.7 (0.7)	0.25
Baecke Sport index	2.6 (1.3)	2.5 (1.1)	0.62
Baecke Leisure Time Index	3.1 (0.6)	2.8 (0.5)	0.58
GHQ12	12.3 (5.6)	11.8 (3.9)	0.11
	N (%)	N (%)	
% not returned to full normal activities	12 (66.7)	66 (79.5)	*0.05

FABQPA; Fear avoidance beliefs (physical activity), FABQW: Fear avoidance beliefs (work), GHQ12: General Health Questionnaire

7.1.5 Predictive association between disability at three months and physical activity

Univariate (linear regression) analyses indicated that none of the baseline measures of activity, or change in activity from baseline to 3 months, predicted RMDQ score at 3 months (Table 7-8). A separate analysis investigated whether change in activity in participants with a low baseline activity, as recorded by the RT3 and 7D-PAR, predicted RMDQ change. For the purposes of this research, low activity was defined as below the mean value for both RT3 VM/hr/week and PAEE (kcals/kg). All measures of PA measurement were not predictive of RMDQ.

Table 7-8 Univariate analyses of physical activity measures as predictors of RMDQ at 3 months

Parameter	B (95% CI)	Sig (p value)
Baseline RT3 VM/r/wk	-4.73E-005 (0.00 to 2.56E-005)	0.20
Baseline PAEE kcals/kg	0.005 (-0.15 to 0.026)	0.59
Report of a return to full activities at baseline	0.071 (-1.144 to 1.54)	0.92
Change in RT3 VM/r/wk from baseline to 3 months	-2.89E-005 (-8.70E-005 to 0.326)	0.33
*RT3VM_change in low RT3 VM/hr group at baseline	3.71E-005 (0.00 to 0.00)	0.62
Change in PAEE kcals/kg from baseline to 3 months	0.046 (-0.096 to 0.188)	0.52
**PAEE kcals/kg change (7D-PAR) in low activity group at baseline	0.009 (- 0.27 to 0.05)	0.63

*Low RT3 VM/r/wk group defined as below the mean RT3 VM/hr/wk at baseline

**Low PAEE group defined as below mean PAEE kcals/kg at baseline

Significant variables in univariate analyses which met the multiple regression inclusion criteria are presented in Table 7-9. Increasing age was found to be the only variable which predicted RMDQ at 3 months; all other variables were not significant predictors of RMDQ score at 3 months.

Table 7-9 Multiple linear regression analyses of significant univariate predictors of RMDQ score at 3 months

Parameter	B (95% CI)	Sig (p value)
FABQPA	0.09 (-.030 to 0.135)	0.14
GHQ12	0.05 (-.123 to 0.581)	0.58
Age (years)	0.06 (0.002 to 0.120)	0.05
RT3 VM change from baseline to 3 months	-2.89E-005 (-8.70E-005 to 0.326)	0.33
Baseline RT3 VM/hr/wk	-3.50E-005 (0.000 to 0.364)	0.36

Note: Model adjusted for sex, occupation, BMI, as well as baseline levels of pain, depression, anxiety, emotional distress and fear avoidance (GHQ12 and FABQ) and activity levels prior to the onset of LBP (Baecke work, sport and leisure scores).

7.1.6 Predictive association between change in disability and change in physical activity

Multiple linear regression analyses including all variables with a p value < 0.1 from the unadjusted analyses and measures of PA change from the RT3 and 7D-PAR are presented in Table 7-10. The singular variable associated with a change in RMDQ was the patient's report of a return to full 'normal' activities at the 3 month point. All measures of PA measurement were not predictive of RMDQ change from baseline to 3 months.

Table 7-10 Multiple linear regression analyses of physical activity measures against RMDQ change

Predictor	βa (95% CI)	p-value	βb (95% CI)	p-value	β (95% CI)	p-value
RT3 VM/hr/wk change	0.00 (0.00 - 0.00)	0.88	0.00 (0.00 - 0.00)	0.85	0.00 (0.00 - 0.00)	0.81
*RT3VM_change (low RT3 VM/hr group)	-2.03E-005 (0.00 - 0.00)	0.85	.000 (0.00 - 0.00)	0.89	.000 (0.005 - 0.006)	0.89
PAEE kcals/kg change (7D-PAR)	-0.014 (-0.08 -0.06)	0.06	0.01 (-0.02 - 0.25)	0.94	-0.01 (-0.41 - 0.02)	0.45
**PAEE kcals/kg change (7D-PAR)	-.027 (-0.07 -0.19)	0.24	0.30 (-0.08 - 0.18)	0.27	0.31 (-0.08 - 0.18)	0.27
Returned to normal activities at 3 months	-3.03 (-5.07--0.99)	< 0.001	-3.33 (-4.69 - 1.97)	< 0.001	-3.14 (-4.64 - 1.65)	< 0.001

βa Regression coefficients adjusted for age, BMI, occupation, activity levels prior to the onset of LBP, fear avoidance, levels of anxiety and depression

Bb Regression coefficients for a backwards selection model which began with all variables where p<.1 for univariate analyses β Regression coefficients adjusted for PA measures and age, BMI, occupation, activity levels prior to the onset of LBP, fear avoidance, levels of anxiety, depression and baseline RMDQ and pain levels.

*Low RT3 VM/r/wk group defined as below the mean RT3 VM/hr/wk at baseline

**Low PAEE group defined as below mean PAEE kcals/kg at baseline

Figure 7-1 shows the RMDQ change score for those with a dichotomised (high/low) RT3 VM/hr/wk change score from baseline to 3 months. High RT3 VM/hr/wk change was determined as greater than the 75th percentile change in RT3 VM/hr/wk. No difference in the RMDQ change score between the two groups from baseline to 3 months (high and low RT3 change score) was apparent.

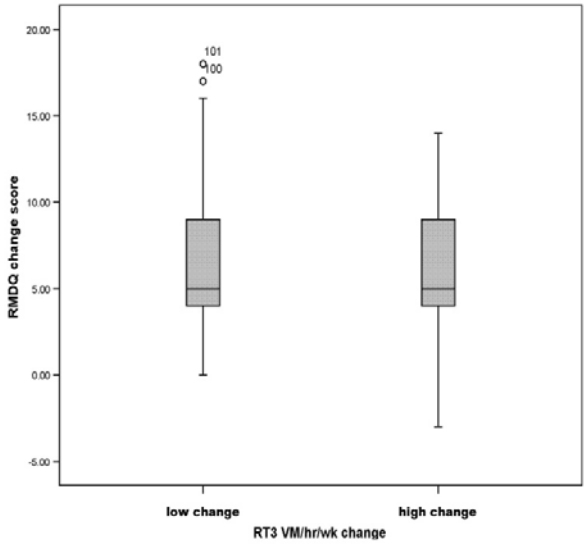

Figure 7-1 RMDQ change score in groups with high and low RT3 change (RT3 VM/hr/wk) from baseline to 3 months

7.1.7 Association between baseline activity measures and baseline LBP disability and pain

Post-hoc analyses were carried out to assess whether activity levels correlated with measures of LBP disability or pain. There was no significant correlation between the objective measures of activity (RT3 VM/hr/wk) at baseline, and RMDQ or VAS scores at baseline (Table 7-11).

Table 7-11 Pearson Correlations between baseline measures of physical activity and baseline RMDQ and VAS scores

	Baseline RMDQ Score (p value)	Baseline VAS Score (p value)
Baseline PAEE kcals/kg (7D-PAR)	-0.19 (0.06)	-0.07 (0.49)
Baseline RT3 VM/hr/wk	-0.14 (0.186)	-0.03 (0.77)

7.1.8 Association between objective measures of activity and patient report

Post-hoc analyses also found no significant correlation between the objective measures of activity (RT3 VM/hr/wk) at baseline and 3 months, and the patient's report of a return to full 'normal' activities at these two time points (Table 7-12).

Table 7-12 Correlations between RT3 VM/hr/wk and patient's report of a return to full normal activities at baseline and 3 months

Kendall's tau_b correlations	Patient report of a return to 'normal' activities (p value)	
Activity measurements	Baseline	3 months
Baseline RT3 VM/hr/wk	0.16 (0.06)	-
3 month RT3 VM/hr/wk	-	0.09 (0.29)
Change in RT3 VM/hr/wk	-0.02 (0.82)	-0.06 (0.47)

7.2 One year results

7.2.1 Differences in baseline measurements in those lost to follow up at one year

At 1 year, 77 participants returned questionnaire data, and there were 24 non-responders (23.7%). Table 7-13 presents the comparison between the baseline characteristics of those participants lost to follow up, compared with those with complete data at 1 year. The only significant difference between the two groups was that those lost to follow up had a higher FABQPA score and a lower percentage reported a return to 'normal' activities at baseline. There was no difference in any of the other baseline variables including measures of PA between the two groups.

Table 7-13 Differences in baseline measures between those lost to follow-up at 1 year and complete data

	1 year data (n = 77) Mean (SD)	Mean Difference (95% CI) of data of missing participants (n = 24)	Paired t-test P value
Age (years)	39.1 9 (14.1)	5.27 (-12.00 - 1.46)	.124
BMI	25.6 (4.4)	-2.03 (-0.17 - 4.23)	.070
RMDQ score at baseline	7.9 (3.8)	-0.41 (-1.37 - 2.20)	.647
VAS score at baseline	58.1 (18.6)	2.81 (-12.00 - 6.37)	.545
FABQPA	13.9 (5.5)	-2.58 (0.09 - 5.06)	.042
FABQW	15.4 (9.1)	-1.89 (-2.44 - 6.24)	.388
Baecke Work Index	2.8 (0.7)	0.12 (-.44 - 0.19)	.427
Baecke Sport index	2.6 (1.1)	0.08 (-.62 - 0.46)	.771
Baecke Leisure Time Index	2.9 (0.5)	-0.08 (-0.18 - 0.34)	.536
GHQ12	11.8 (4.2)	-0.42 (-1.5 - 2.4)	.667
Baseline Daily PAEE kcals/kg (7D-PAR)	14.5 (3.1)	-0.68 (-1.9 - 2.2)	.736
Baseline RT3 VM/hr/week	25522	-1800.61 (-7522.5 - 3921.3)	.533
	N (%)	N (%)	
Gender (females)	39 (51%)	12 (50%)	0.95
Occupation (% manual)	35 (46%)	9 (38%)	0.07
Returned to full 'normal' activities at baseline	20 (26%)	3 (12.5%)	0.02

FABQPA; Fear avoidance beliefs (physical activity), FABQW: Fear avoidance beliefs (work),

7.2.2 Low back pain outcomes at one year

Table 7-14 shows results for the Nordic Musculoskeletal questionnaire at 1 year. Approximately 47% of participants considered that their LBP had resolved at this time point, while the remaining 53% reported that the LBP was unresolved, chronic, or on-going. While the majority of participants had at least two further episodes of LBP over the 1-year period (84%), only a small percentage required time off work as a result of this recurrence (10%). The vast majority reported no new injury to their back, and only 36% had sought further treatment for their LBP over the past year.

Table 7-14 Nordic Questionnaire results at 1 year

Nordic Questionnaire	Symptoms reported	Number (n = 77) (%)
LBP at 1 year (Y/N)	LBP resolved	36 (46.8)
	LBP persistent chronic or ongoing and on-going	41 (53.2)
LBP episodes over previous 1 year	none	6 (7.8)
	1 episode	6 (7.8)
	2-5 episodes	35 (45.5)
	6-10 episodes	9 (11.7)
	> 10 episodes	21 (27.3)
Time off work over the last year due to LBP	none	69 (89.6)
	1to 4 weeks	1 (1.3)
	1-3 months	6 (7.8)
	4-6 months	1 (1.3)
Report of a new injury	no new injury	66 (85.7)
	new injury	11 (14.3)
LBP requiring treatment over last year	no treatment	49 (63.6)
	required treatment	28 (36.4)

7.2.3 Comparison of low back pain outcomes at baseline, three months, and one year

Results for the main outcome measures show that there was no difference between the outcome measures at 3 months compared to 1 year (Table 7-15).

Table 7-15 Results of main outcome measure at baseline, 3 months, and 1 year

	Baseline Mean (SD)	3 months Mean (SD)	1 year Mean (SD)	**P value between 3 months and 1 year
RMDQ score	8.1 (3.8)	1.7 (2.9)	1.83 (2.4)	0.72
VAS score	57.4 (19.7)	15.2 (19.6)	18.4 (17.1)	0.45
	N (%)	N (%)		N (%)
Returned to normal activities	23 (22.8)	69 (68.4)	60 (77.9)	*0.32

*McNeer's test

** T-tests

7.2.4 Comparison of levels of activity from baseline to 1 year

There was no difference in the levels of leisure time, sports, or work activity between baseline (pre-LBP) and at 1-year, as recorded from the BPAQ (Table 7-16).

Table 7-16 Comparison of Baecke activity scores at baseline and 1 year

Baecke Score	Baseline (n = 101)		1 year (n = 77)		Paired t-tests
	Range	Mean (SD)	Range	Mean (SD)	P value
Baecke Work Index	1.42 to 4.15	2.81 (0.68)	1.61 - 4.59	2.79 (0.64)	0.38
Baecke Sport index	0.86 - 5.85	2.59 (1.17)	0.83 - 74	2.62 (1.23)	0.86
Baecke Leisure Time Index	1.87 - 4.52	2.91 (0.57)	1.32 - 4.36	2.87 (0.59)	0.71

There was a significant difference in levels of sport activity (Baecke Sport Index score) between those with resolved LBP versus those who were unresolved at 1 year (Table 7-17).

Table 7-17 Comparison of Baecke activity scores in resolved LBP patients and patients with persistent LBP at 1 year

Baecke Score	LBP resolved (n = 36) Mean (SD)	LBP persistent chronic (n = 41) Mean (SD)	Mean Diff (95% CI)	P value
Baecke Work Index	2.71 (0.69)	2.88 (0.59)	-0.17 (-0.46 to 0.12)	0.25
Baecke Sport index	2.93 (1.38)	2.36 (1.05)	0.56 (0.01- 1.12)	0.04*
Baecke Leisure Time Index	2.92 (0.68)	2.83 (0.51)	0.09 (-0.19 – 0.36)	0.53

There was also a significance difference in Baecke Sport Index score at 1 year in those with a significant change in RMDQ score at 1 year, compared to those with a non-significant RMDQ change score (Table 7-18). There was no difference in the Baecke leisure and work scores between the two groups.

Table 7-18 Comparison of Baecke activity scores in patients with significant RMDQ change score at 1 year.

Baecke Score	RMDQ < 4 (n = 61) Mean(SD)	RMDQ > 4 (n = 16) Mean (SD)	Mean Diff (95% CI)	P value
Baecke Work Index	2.73 (0.63)	3.03 (0.64)	0.29 (-0.06 - 0.65)	0.10
Baecke Sport index	2.81(1.23)	1.92 (1.00)	-0.89 (-1.55 - -0.22)	0.01*
Baecke Leisure Time Index	2.91 (0.59)	2.72 (0.62)	-0.19 (-0.52 - 0.14)	0.26

Change in activity over the year showed a lowering of both work and leisure index scores at 1 year in those with persistent LBP. There was no change in any of the Baecke measures of activity over the 1 year period in the patients reporting that their LBP had resolved (Table 7-19).

Table 7-19 Comparison of Baecke change scores from baseline to 1 year in patients with resolved LBP and patients with persistent LBP

Self report by patient (Y/N)	Baecke Questionnaire	Mean difference (SD)	95% CI	p value
LBP resolved	Baecke Work Index	0.06 (0.44)	-0.20 - 0.09	0.46
	Baecke Sport index	0.13 (0.87)	-0.42 -	0.38
	Baecke Leisure Time Index	0.14 (0.6)	-0.34 - 0.06	0.17
LBP persistent chronic and/or on-going	Baecke Work Index	-0.14 (0.52)	-0.02 - 0.30	0.09
	Baecke Sport index	-0.08 (0.72)	-0.15 -	0.47
	Baecke Leisure Time Index	-0.17 (0.62)	-0.03 - 0.37	0.09

7.2.5 Association between outcome measures at one year and change in activity from baseline to one year

Correlations between the main outcome measures at 1-year were all significant, and demonstrated moderate to good correlations with each other (r = -0.47 to 0.61). Change in PA, as measured with the BPAQ, demonstrated only low correlations (r = 0.2 to 0.28) with the outcome measures at 1 year (Table 7-20).

Table 7-20 Pearson correlations between outcome measures at 1 year

LBP outcome measure	RMDQ score at 1 year	Return to normal activities at 1 year	LBP resolution at 1 year
BPAQ change score	-0.27 (0.02)	0.20 (0.08)	-0.28 (0.01)
RMDQ score at 1 year		-0.60 (< 0.001)	0.61 (< 0.001)
Return to normal activities at 1 year			-0.47 (< 0.001)

There was a significant difference in RMDQ score from baseline to 1 year as well as significant differences in RMDQ change scores, and in report of a return to full activities between participants with unresolved LBP compared to participants who reported that LBP had resolved at 1 year (Table 7-21).

Table 7-21 Comparison of RMDQ scores and return to normal activities and Nordic LBP questionnaire

Outcome Measures	LBP resolved Mean (SD)	LBP persistent chronic and on-going Mean (SD)	P value
RMDQ score at 1-year	0.28 (0.66)	3.20 (2.56)	<.0001
RMDQ change score from baseline to 1 year	7.33 (3.69)	5.07 (4.77)	0.02
Returned to normal activities at 1 year	35 (100%) **	25 (62%) **	0.007*

*McNemar's test

** One missing data set

7.2.6 Predictors of RMDQ at one year

Table 7-22 shows the significant variables in univariate regression analyses for predictors of RMDQ at 1 year. A patient report of not returning to full 'normal' activities at baseline was a significant predictor of an increased RMDQ score at 1 year. A lower Fear Avoidance Beliefs Questionnaire Work (FABQW) and VAS pain score at baseline predicted a lower RMDQ change at 1 year. No PA measurements predicted RMDQ at 1 year in univariate analyses.

Table 7-22 Univariate analyses of significant predictors of RMDQ change score (baseline to 1 year)

Predictors	B (95% CI) 95% Confidence Interval	Sig.
Non manual occupation	5.28 (-0.01 - 10.58)	0.05
Not returned to full 'normal' activities at baseline	3.82 (1.69 - 5.95)	<0.001
VAS score at baseline	0.09 (0.04 - 0.14)	<0.001
FABQW score	0.12 (0.02 - 0.23)	0.02

B regression co-efficient; VAS Visual Analogue Scale; FABQW Fear Avoidance Beliefs Work score

In multiple regression analyses the only variable to predict RMDQ at 1 year was a lower FABQW score at baseline (Table 7-23). None of the measures of PA at baseline, 3 months predicted RMDQ at 1 year.

Table 7-23 Multiple linear regression analyses for significant predictors of RMDQ change from baseline to 1 year

Predictor	B (95% CI) 95% Confidence Interval	Sig. (p value)
FABQW	0.07 (0.03 to 1.42)	.040

B adjusted for age, BMI, occupation, activity levels prior to the onset of LBP, Fear avoidance, levels of anxiety, depression RMDQ scores and VAS pain levels at baseline and PA levels (RT3 and 7D-PAR) at baseline and 3 months.

7.2.7 Predictors of low back pain chronicity at 1 year

Table 7-24 shows the significant variables in univariate regression analyses for predictors of on-going recurrent LBP (Y/N) at 1 year. A number of measures of activity predicted a report of chronicity at 1 year including: a lower Baecke Sports Index score at 1 year, a lower change in PA from baseline to 1 year (BPAQ change), and a higher work activity score at baseline. The report of not returning to full normal activities at 3 months explained 9.0% of the variance in chronic LBP at 1 year. A higher VAS score at 3 months explained 17.0% of the variance in on-going LBP at 1 year.

Table 7-24 Univariate predictors of chronic or on-going LBP resolved at 1 year (Y/N)

Predictors	B	R2	Sig.	Exp(B)	95.0% C.I.for Exp (B)	
					lower	upper
VAS score at 3 months	.056	0.17	.002	1.05	1.02	1.09
Self-report of not returned to full normal activities at 3 months	1.49	0.09	.018	4.44	1.29	15.28
Baecke Work Index (pre LBP)	1.06	0.06	.008	2.90	1.31	6.43
Baecke Sports index score at 1 year	-.39	0.05	.051	.67	0.45	1.00
BPAQ change	-0.47	0.07	0.02	0.62	0.42	0.92

Adjusted for age, BMI, occupation, activity levels prior to the onset of LBP, fear avoidance, levels of anxiety, depression and baseline and 3 month RMDQ scores and VAS pain levels at baseline and 3 months and PA levels (RT3 and 7D-PAR) at baseline and 3 months .

In multiple analyses (Table 7-25) the only significant predictor of LBP at 1 year was a higher level of pain reported at 3 months. The histogram below (Figure 7-2) demonstrates that those who reported chronic LBP at 1 year had a significantly higher VAS score at 3 months

compared to those who reported resolution of LBP at 1 year. None of the activity measures at baseline, 3 months, or 1 year predicted resolution of LBP at 1-year.

Table 7-25 Multiple regression analyses for predictors of chronic LBP at 1 year

Predictors	B	Exp(B)	95.0% C.I.for EXP(B)	P value
VAS score at 3 months	0.05	1.05	1.01 to 1.10	.002

B Adjusted for age, BMI, occupation, activity levels prior to the onset of LBP, fear avoidance, Levels of anxiety, depression and baseline and 3 month RMDQ scores and VAS pain levels at baseline and 3 months and PA levels (RT3 and 7D-PAR) at baseline and 3 months, BPAQ baseline and 1 year

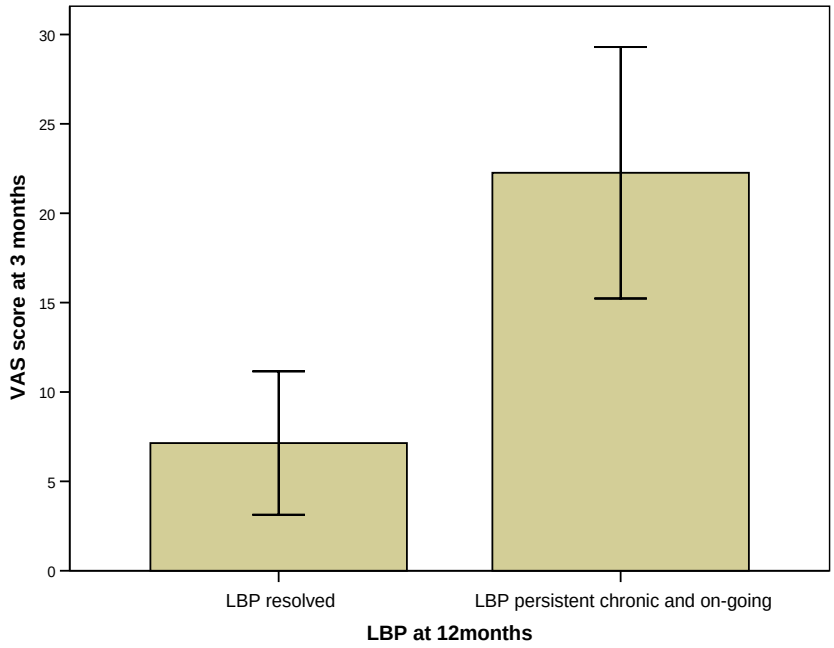

Figure 7-2 Bar chart with SD showing the association between VAS pain score/100 at 3 months and resolution of LBP at 1 year

7.3 Discussion

This study investigated the predictive associations between objective and non-objective measures of physical activity and LBP disability at 3 months and 1 year. Measures of PA at baseline and change in PA as measured by either the RT3 or a recall questionnaire (7D-PAR) did not predict either RMDQ score at 3 months, or change in RMDQ from baseline to 3 months. This study also found no differences in levels, reported types, or intensities of activity, at either baseline or at 3 months, measured with the RT3 or recall questionnaire. None of the measures of PA at baseline or 3 months predicted RMDQ at 1 year. However, a number of measures of activity were found to predict chronic LBP at 1 year in univariate analysis: a patient's self-report of not returning to full normal activities at 3 months; a higher

Baecke Work Index (pre LBP) and a lower Baecke Sports Index score at 1 year; as well as a lower overall change in activity (as measured from the BPAQ); all predicted a patient report of on-going chronic LBP at 1 year in the univariate model. However, none of the measures of activity were found to predict chronic ongoing LBP when multiple analyses were performed.

7.3.1 Three month results

There have been no previous investigations of the association between activity levels and disability within an acute LBP population over this time frame. Importantly, this study investigated the associations between both baseline activity measures (employing an objective measure and a recall questionnaire) and change in baseline measures of activity, with both disability and change in disability from baseline to 3 months and at 1 year. None of the measures of activity predicted RMDQ at 3 months or change in RMDQ in the univariate or multiple regression models. Increasing age was the only predictor of RMDQ score at 3 months in the multiple regression model, and the report of full 'normal' activities at 3 months correlated with change in RMDQ from baseline to 3 months.

Although a recent cross-sectional study of a chronic LBP population found that activity fluctuation was a significant contributor to disability, rather than average levels of diary recorded activity (Huijnen, Verbunt et al. 2009), the current study found no difference in variability of activity levels (SD of RT3 VM counts/hr) from baseline to 3 months, and consequently no predictive association to RMDQ over this time frame. The lack of an observed association between activity variability and disability may be due to the relatively high levels of activity in the current study, and the lower disability levels in comparison to Huijnen, Verbunt et al. (2009).

Although the majority of participants reported that they had not returned to "normal" activity levels at baseline, it is possible that their actual levels of activity may have been relatively "normal" at this time point. Results also indicated that baseline activity was not correlated with LBP disability or pain levels, and that a report of "normal' activities was not correlated with activity levels at the two time points. Therefore in order to investigate the potential for those with lower activity at baseline to have greater potential to change their activity (and thus to more likely show an association with RMDQ at 3 months), this variable was dichotomised into high and low levels of activity. No predictive association was found between change in activity in the low activity at baseline group with either RMDQ or change in RMDQ at 3 months. The multiple regression model also included activity levels prior to the onset of LBP

as potential confounders to the association between PA and RMDQ; however sample size provided insufficient power to investigate for interaction effects between prior activity levels and activity levels during the episode of LBP and levels of LBP disability. The lack of observed change in activity from baseline to 3 months may be due to the low to moderate RMDQ scores at baseline (8.5) and a majority continuing to work. Thus these results can not be generalised to LBP populations with higher levels of disability, or to those who are unable to work.

This study found no change in the types of activity at 3 months from those described at baseline. Despite this, a significant change was observed in all main outcome measures, with 84% of those with complete data having an RMDQ score < 4.0 at 3 months, with both a significant and clinically meaningful change in RMDQ and VAS scores (Table 7-4). Bousema et al. 2007 reported that levels of PA increased over one year for both chronic (19.7%) and recovered (12.6%) patients, although there was no difference between the activity levels over time. Other studies have reported increases in levels of PA, employed as an outcome measure, in various intervention trials (McCracken, Gross et al. 2002; Basler, Luckmann et al. 2008; Leonhardt, Keller et al. 2008). As the present trial included participants who were undergoing physiotherapy interventions during the data collection period, it is not known whether the lack of a change in activity is due to a selection bias, in that participants were already motivated and relatively active at baseline, and therefore levels of reported activity were relatively high (Bennett, Winters-Stone et al. 2006). Alternatively, it may be that these physiotherapy interventions did not result in a change in the participant's PA behaviour at 3 months during the period of physiotherapy intervention.

Non-objective measures of activity at baseline and 3 months from the 7D-PAR (kcal/kg/day) were slightly higher than that recorded with the 7D-PAR from a healthy working community of similar age range (Ekelund, Sepp et al. 2006). The percentage in manual occupation (44%) was also relatively high, and the majority continuing to work despite LBP was undoubtedly a factor in the high activity levels at baseline. Previous research has demonstrated the importance of PA at work in maintaining or meeting health-related PA guidelines, particularly within blue collar workers (Mark, Merom et al. 2008). Therefore these results can not be generalised to LBP populations who are unable to work.

A patient report of a return to full 'normal' activities at 3 months was associated with RMDQ change from baseline to 3 months. This finding has not previously been reported, perhaps

reflecting the 24 item RMDQ predominantly assessing activity limitations (Grotle, Brox et al. 2004), and being better targeted at populations with moderate or high disability, similar to our group at baseline (Davidson 2009). A significant proportion at baseline reported that they had not returned to "normal" activities, a finding similar to previous research which showed that LBP patients feel some degree of limitation in activities of daily living correlating to the degree of disability (Lee, Simmonds et al. 2001). Thus early return to "normal" activities was not an independent predictor of either disability or change in disability at 3 months. The potential reasons for these findings may be due to the complex nature of the disablement process, thought of as a gap between personal capability and environmental demand (Verbrugge and Jette 1994). The effects of PA and disability have been found to be mediated by a range of factors including pain, fatigue and depression, and self- efficacy (Burke, Beilin et al. 2008; Motl, McAuley et al. 2009), as well as a range of specific performance measures including trunk flexion and extension, hip, knee and foot pain, and depression (Di Iorio, Abate et al. 2007). Further investigation is therefore required to study the potential effects of other mediators in the association between activity, disability, and functional limitation

Interestingly, there was no association at either time point between the patient's recorded activity levels and a report of a return to full "normal" activities at 3 months. These results suggest that the patient's perceived (rather than actual) levels of activity are important predictors of recovery. Perceived activity decline has previously shown a significant association with disability, fear of injury, depression, and pain intensity (Verbunt, Seelen et al. 2005). Bousema et al. 2007 also reported that the patient's perceived level of PA decline predicted actual PA change at 1 year. The association between patients' report of activity normalisation and perceived activity decline warrants further study.

7.4 One year results

At 1 year the only predictor of a lower RMDQ was a lower FABQW score at baseline. None of the measures of activity either prior to the LBP episode, at baseline, 3 months, or at 1 year were associated with RMDQ score at 1 year. However, a number of self report activity measures at baseline, 3 months and 1 year were independent predictors of LBP chronicity: a patient's self-report of not returning to full normal activities at 3 months; a higher Baecke Work Index (pre LBP) and a lower Baecke Sports Index score at 1 year; as well as a lower overall change in activity from baseline to 1 year, were associated with a patient's report of on-going chronic LBP at 1 year. However, none of these PA variables were significant

predictors in the multiple regression model when controlling for factors including age, BMI, occupation, fear avoidance, levels of anxiety, depression, disability, and pain levels. Thus potential influences of PA on chronicity at 1 year appear to be a complex interaction with other predictor variables, and suggest that sports activity maybe a more important correlate of a return to full activities in the long term, and that potential interactions of reported sports activity on disability are confounded by other significant variables in the model. Further research investigating various types of sports participation and activity and long-term disability in LBP populations is therefore warranted.

The one year results found relatively high numbers of participants reporting on-going or chronic symptoms (53%), although the mean RMDQ at this point was relatively low (1.8). These results are similar to previous prospective studies in acute LBP populations (Grotle, Brox et al. 2007), and re-enforce the notion that LBP is characterised by remissions and exacerbations, and that on-going symptoms are common (Majid and Truumees 2008). These results also highlight the importance of measuring both point prevalence and overall LBP episodes in prospective research.

The levels of PA as recorded by the BPAQ, particularly the work and sports index scores at baseline and 1-year, were higher than reported in previous chronic LBP populations (Nielens and Plaghki 2001; Smeets, van Geel et al. 2009), although relatively similar to an acute and sub-acute LBP population (Jacob, Baras et al. 2004), and to a non-disabled free-living adult population (Pols, Peeters et al. 1995). However, the validity of the BPAQ to accurately capture activity in populations of moderate activity, similar to the current population, has been shown to be subject to error (Hertogh, Monninkhof et al. 2008). Therefore the lack of difference in PA at 1-year maybe due to the poor discriminatory ability of the questionnaire within this activity grouping, as well as issues of reporting bias, whereby over and under estimation of various types of activity have been reported with the use of self-report measures of PA (Prince, Adamo et al. 2008).

Previous cross-sectional research within a large sample population (> 8,000) employing the Nordic questionnaire (Heneweer, Vanhees et al. 2009) found no association between daily activities as recorded from the Short Questionnaire to Assess Health enhancing activity and the odds of chronic LBP (Y/N). This group did report that engagement within sports resulted in a lower OR of chronic LBP (0.72), and overall total PA (both high and low) resulted in an increased OR of chronic LBP, which was particularly marked in females. Although a multiple

regression analysis did not find any predictive association between PA measured at 1 year and resolution of LBP, univariate analysis at 1 year did show a positive role for sports participation. The smaller numbers of participants in the current research may be the reason for the non-significant association between PA and LBP resolution.

Prospective research investigating the association between activity and LBP outcomes found no difference in LBP outcomes or recurrence rates during follow up at 5 years in men and women ascribed to low, medium, and high exercise groups at baseline (Mortimer, Pernold et al. 2006); similarly, Jacob et al 2004a employing a single measure of activity at baseline (Baecke questionnaire) also found no association with LBP outcome (modified RMDQ) at 1-year. The current study population were significantly younger than the Jacob et al population (mean age 37.4 versus mean age 46 years), and also much less disabled when compared at 1-year (modified RMDQ score mean at 1 year 6.9 versus 1.8), although activity levels measured with the BPAQ both at baseline and 1 year were comparable. Despite such differences, the current study also found no association with activity measures at baseline, 3 months, and RMDQ at 1 year, or resolution of LBP at 1 year in multiple regression analyses. These results suggest that both objective and self-report measurements of PA are not predictors of LBP outcomes in a range of patient populations, disability, and activity levels.

The current study found no difference in the types of work, leisure, or sports activities from baseline to 1-year within the cohort as a whole; however, a decrease in the work and leisure activity score were noted in the population who reported on-going LBP symptoms at 1 year. A previous study reported changes in the types and total amounts of activity within a chronic LBP population sample, randomised to various intervention groups for activity counselling (Leonhardt, Keller et al. 2008). Over the course of the study both sports and leisure activities increased in all three intervention groups at 6 months and 1 year, but changes in self-reported basic activities fell in all three groups at 6 months, and returned to baseline levels at 1 year. The differences in activity changes between the two studies may be due to a number of factors including: the higher mean age and heterogeneity of the Leonhardt et al. 2008 study population, difference in PA measures, and possible differences in the occupational status between the two studies, as type of occupation was not specified by Leonhardt et al 2008.

This study found that change in PA measured with the BPAQ from baseline to 1 year correlated with both RMDQ score at 1 year ($r = -0.27$) and resolution of LBP at 1 year ($r = -0.28$). Verbunt et al. 2008 devised the PA decline score as a measure of self-reported activity

to investigate the correlation with the change in BPAQ score over a one year period in a cohort of patients with chronic LBP. They reported that measured change in activity was significantly associated with the self-report of activity decline (r = 0.45), and also that PA change was significantly associated with disability levels at 1 year (r = 0.4). Although the current study found only low to moderate correlations with LBP outcome measures at 1 year, both studies confirm the potential association between self-report activity measure decline and long term disability; however the effect was less significant in the current study.

Findings from the current study suggest that the effects of the various types of physiotherapy treatment (which were not recorded) did not result in a change in overall activity levels pre- to post-LBP or over the one year measurement period. Numerous research studies have shown increases in dimensions of PA following various types of intervention (Tollison, Satterthwaite et al. 1990; Ghoname, Craig et al. 1999; Sator-Katzenschlager, Scharbert et al. 2004) However, all these studies measured PA immediately post-intervention, and therefore the lack of observed change in the current research may be a reflection of the measurement points (baseline, 3 months, and 1 year), as well as the measurement method. Research has also found increases in both the levels and types of non-objectively measured PA within LBP populations after intervention over various time periods (Bendix, Bendix et al. 1998; Carlsson and Sjolund 2001; Arokoski, Juntunen et al. 2002; Becker, Leonhardt et al. 2008). Changes in the types and dimensions of activity at 1-year within a mixed cohort of manual workers undergoing a functional rehabilitation programme were found to be principally dependent upon type of occupation (Arokoski, Juntunen et al. 2002). Although occupation was not found to be a predictor of PA change at 1 year in the current study, the association between activity change and occupational grouping was not investigated, as the heterogeneity of occupational groups only allowed dichotomisation of the occupational variable into manual versus non-manual. Therefore it is not possible to fully evaluate the effects of occupation as a potential mediating factor in activity change within this cohort. It might also be that the use of PA as an outcome measure was a motivating factor in these studies, compared to the current study where activity was measured in an observational design.

7.5 Conclusions

These results show that activity levels do not predict recovery at 3 months and 1 year in a cohort of patients with acute LBP. There was also no difference in the levels or types of activity during a period of acute LBP compared to 3 months post-episode, and no difference

in activity levels from baseline to 1 year. None of the measures of activity at baseline, 3 months, or 1 year predicted functional disability or resolution of LBP at 1 year. However, differences in the changes in activity were observed in participants with on-going LBP. Further research is required within larger, higher powered studies to investigate the complex interactions between activity and their importance in patient outcomes. These results also question the widely held assumption that activity levels change as LBP symptoms resolve, and the potential role that physical activity plays in LBP recovery. The patient's report of a return to full activities predicted functional disability, and therefore focus on activity normalisation during rehabilitation, rather than increasing activity per se, may offer the best opportunity for success in improving patient outcomes.

CHAPTER VIII

General Discussion

8 General Discussion

The systematic review (Chapter IV) and the main study undertaken for this thesis found no evidence for a association between activity and LBP outcomes, and neither objective nor self-report measures of activity predicted LBP outcomes in either the short or long term. The strength of such findings are supported by the design of the study: being powered to detect a minimal clinically important difference (MCID) in the RMDQ, coupled with the very high response rate at 3 months; the relatively low levels of activity data loss over the measurement period (Chapter V); and the use of multiple PA measurement tools and time points (Cervantes and Porretta 2010) to investigate potential associations to LBP outcomes. However, it is acknowledged that there are a number of factors (discussed below) which can affect the validity of free living PA measurement (Besson, Brage et al. 2010), particularly when investigating longitudinally potential associations with health outcomes (Cole and Maxwell 2003). The following discussion relates primarily to the main study results in relation to the current understanding of the role of activity in LBP recovery.

8.1 Validity of activity measurements

Chapter II discussed the strengths and limitations of the various methodologies currently employed to measure free living activity. It was acknowledged that an accurate estimation of PA requires limiting the amount of error in the measurement system (Baranowski and de Moor 2000), monitoring compliance in terms of wearing the accelerometer or self-recording of PA (Coleman and Epstein 1998; Conn, Minor et al. 2000), and is dependent upon the homogeneity of the population and the measuring device. The current study attempted to address these issues by adoption of a recommended protocol for measurement of PA employing an accelerometer in free living (Ward, Evenson et al. 2005; Welk 2005). The study protocol included standardised testing of the monitors prior to use, performing standardised tests to replicate study conditions, ensuring that each participant received the same unit on retest, adoption of a standardised PA protocol, requiring a minimum recording period for inclusion, use of multiple measures including an activity log to measure PA, and a repeated measures design to improve the internal validity of the study (Gebruers, Vanroy et al. 2010). Monitor wear and placement were standardised and number of days and hours of RT3 data were in agreement with current recommendations for field measurement of activity (Troiano,

Berrigan et al. 2008). Participants were also required to record days and times of wear (and sleep times) as well as reasons for removal of the RT3 within their activity diary. Compliance to wear was improved by regular contact (at least twice a week), letters and phone calls prior to the second monitoring period, and the use of a $10 dollar voucher on completion of the second week of monitoring, and to ensure optimal compliance with the activity measurement from results discussed in Chapter V. Although no research has investigated the effects of such measures on compliance to wear, it can be argued that such measures were instrumental in minimising data loss in this study due to non-adherence to wear and drop out.

Participant drop out and technical issues with the RT3, as previously reported in the literature (Hertzog, Nieveen et al. 2007; Sloane, Snyder et al. 2009), remained the main cause for data loss over the two measurement points. As such data appeared to be missing completely at random, and not affected by the participant's activity levels, it is estimated that such data loss had minimal effect upon the internal validity of the results. Also, the 82% success rate for RT3 data completion compares very favourably with other studies which have utilised the RT3 in free living PA measurement (Hertzog, Nieveen et al. 2007; Chen, Jerome et al. 2009; Hecht, Ma et al. 2009; Hollowell, Willis et al. 2009). A previous study of a cohort undergoing a weight loss programme also found that when employing a minimum requirement for 4 or more 10 hour days (including 1 day on the weekend) of monitoring, 82% of participants provided completed RT3 data (Chen, Jerome et al. 2009). Another study within a similarly aged population as the current study reported very high levels of data loss, due to either RT3 malfunction, insufficient wear time, losing the device, or the battery dying (Hollowell, Willis et al. 2009). Much lower levels of compliance and higher levels of data loss were found in an elderly population which required at least 10 hours/day of RT3 data to be recorded over three days on three separate occasions (Hertzog, Nieveen et al. 2007). They also reported that 51 units were required over the collection period due to the fact that 35 had to be returned for cleaning, and 20 needed replacements due to either loss or malfunction. In the current study 10 units were employed at the start of the study; however, due to participant loss and RT3 malfunction, a further five units were required as replacement. Over the study period, due to the relatively low loss of RT3 devices and malfunctions, it was possible to ensure that 80% of participants had the same RT3 at baseline and at 3 months, thus reducing potential bias due to the recognised higher levels of RT3 inter monitor reliability (King, Torres et al. 2004).

Management of missing data in free living PA measurement with an accelerometer is problematic (Marshall, De La Cruz-Mesía et al. 2009). The current study recorded and

itemised all missing data periods manually in order to determine reasons for, and types of, data loss, and did not employ statistical programs to identify and classify non-wear periods and missing data, as has been previously employed (Paul, Kramer et al. 2008; Troiano, Berrigan et al. 2008) Such a process may potentially be more accurate in minimising error in the management of missing data, however it is argued that the current methods are unlikely to have resulted in a systemic bias, since it is estimated that such data was missing completely at random. The statistical analyses employed mixed models to investigate potential associations between PA and LBP outcomes; such analyses give unbiased and consistent estimates when the data are missing at random (Mallinckrodt, Lane et al. 2008). It is also recognised that a range of single and multiple imputation methods are available for management of missing accelerometry data (Catellier, Hannan et al. 2005), and the use of different imputation methods for missing data may potentially have altered activity levels recorded. However, the relatively high RT3 wear hours and compliance rates, coupled with the low data loss, strongly suggests that the current management of missing data is unlikely to have altered the results. Also, the main PA measure employed (RT3 VM/hr/wk) was time normalised to account for unequal wear time, and as such provided a more valid representation of PA levels (Ward, Evenson et al. 2005). The agreement between the objective and self-report measurements (7D-PAR) at all three time points further validates the findings of non-significant activity change in this patient population at the three time points.

The study employed a range of self-report measurements to record participants' activity levels at the three time points. There are a number of limitations (discussed in Chapter II and III) for the use of such measurements (Warren, Ekelund et al. 2010) to record and capture free living PA. This study also employed a simple questionnaire to ascertain whether participants considered that they had returned to "normal" activities since the episode of LBP. This question was included in response to current LBP guidelines which emphasise "normalisation" of activities following a LBP episode (Arnau, Vallano et al. 2006). This measure is somewhat problematic as such a dichotomous variable does not capture which precise aspects of activity have changed or normalised. Although the majority of participants reported that they had not yet returned to "normal" activity levels at baseline, it is possible that their actual levels of activity may have been relatively "normal" at this time point. This finding is further supported by the self-report of a return to 'normal" activities not correlating with measured activity levels. Further analyses found no predictive association between activity levels in those with lower activity levels at baseline and outcome measures at 3 months. These findings suggest that a patient's perception of normalisation of activity may

not necessarily relate to the amount or type of activity, but perhaps the level of difficulty or perceived difficulty of the activity in relation to their LBP symptoms. However, further research is required to more fully investigate this phenomenon.

8.2 Measurement of confounding factors

The main study for this thesis included a number of potential confounding factors that have been putatively associated with LBP chronicity and functional disability in the multiple regression models. Since the main purpose of the research was to assess whether activity or change in activity predicted functional disability from LBP, not all potential LBP prognostic factors were included in the statistical study model (Pincus, Santos et al. 2008). Variables were included based upon previous research, which showed them to have strong levels of evidence as potential confounders to the association between activity and LBP outcomes (Chapter III and IV). Therefore, for pragmatic reasons, time constraints and power calculations an estimated 80 to 120 participants were planned for recruitment. Thus, based upon the accepted inclusion of one confounder for 10 subjects (Siemiatycki, Krewski et al. 2003) allowed six to eight variables with the highest strength as potential confounders to be included in the analysis. Research suggests that a number of behavioural and psychological variables are predictive factors of activity limitations within acute pain populations (Al-Obaidi, Al-Zoabi et al. 2003; Molloy, Sniehotta et al. 2009). Therefore, a larger prospective study would allow further exploration of the effect of confounding and behavioural mediating factors on activity and LBP.

8.3 Variance in activity measures

The capture of PA requires a reliable estimate of the normal variance of PA within the studied population (Matthews, Ainsworth et al. 2002). Pilot testing demonstrated that the RT3 was able to reliably measure PA in a repeat measures design using at least five days of data collection and one weekend day within a normal population (see Chapter V for further discussion). Based upon these findings it was estimated that the variance of PA within a LBP population would be of a similar or lower level, and that such variability would increase as symptoms resolved (Spenkelink, Hutten et al. 2002). However, there was no change in the variability in PA (SD RT3 VM/hr/wk) at the later two time points. This finding was a little surprising but perhaps a reflection of the relatively high levels of activity within this acute LBP population at baseline. Research has also shown that variance and variability in PA

measurements is dependent upon a number of factors: these include the types and frequency of the activity levels of the participants (Levin, Jacobs et al. 1999; Matthews, Freedson et al. 2000), sex and age of the participants (Buchowski, Acra et al. 2004), seasonal variation (Levin, Jacobs et al. 1999), activity output and type of measurement tool employed (Baranowski, Smith et al. 1999), as well as occupation (Matthews, Hebert et al. 2001), levels of disability (Spenkelink, Hutten et al. 2002), and behavioural or psychosocial factors (Perruccio, Power et al. 2005). It may be that behavioural factors, particularly in relation to the patient's activity levels during the acute LBP episode, negated any potential effect of disability on variability in activity levels. Also, age, sex, occupation, and activity levels were not predictors of LBP disability, and therefore unlikely to be potential confounders in the association between PA and LBP outcomes in the current study. The potential mediating or moderating interactions of these variables on the association between activity and LBP require further analysis in a larger, more appropriately powered study design.

Previous studies have found that the amount, type, and intensity of activity can vary between seasons (Matthews, Hebert et al. 2001), and particularly when comparing spring/summer with autumn/winter (Pivarnik, Reeves et al. 2003). In this study, the accelerometry measurement part of the study was carried out over twelve months, and it is anticipated that any variations in PA as a result of seasonal variation would be accounted for (balanced) by this design (Hollowell, Willis et al. 2009).

Activity monitoring per se has previously shown potential behavioural effects on levels of activity (van Sluijs, van Poppel et al. 2006), in that the measurement process can positively influence participant's activity levels; i.e. the so-called Hawthorne effect. This process has been observed particularly in self-reporting and pedometer use (Clemes, Matchett et al. 2008), however such reactivity to measurement has been disputed (Behrens and Dinger 2007; Craig, Tudor-Locke et al.). The pilot study (Chapter V) carried out on healthy normal individuals found no evidence for reactivity to measurement, and no difference in activity levels on the first days of measurement in comparison to other days of measurement. Since no significant difference was found in activity levels at the two time points, it is likely that there was no reactivity to wearing the accelerometer in the LBP population, and that this was therefore not a factor in the non-significant association between activity change and LBP

8.4 Activity measurement points in low back pain populations

The systematic review (Chapter IV) identified that few studies employed multiple measurement points to assess the association between activity and LBP outcomes, and thus the assessment of these associations are likely to be in a state of flux. Further exploration of potential associations needs to consider "temporal stability" when describing the observed variance (and co-variance) between activity and LBP outcomes at discreet points in time (Cole and Maxwell 2003). Therefore the timing of assessments to examine the effects of such a association is critical. Investigation of such potential associations may require continual and sequential monitoring of not only activity, but also pain and disability (activity limitation) in order for such potential effects to be more thoroughly explored. Thus it is possible that the measurement process was not able capture these inter-associations, as three distinct, fixed temporal points were chosen to assess activity and disability levels. Monitoring of changes in both pain and disability may require continual assessment of both variables in an on-going manner to better explore the temporal interactions between these two complex factors.

8.5 Validity of outcome measures

The main study investigated the associations between activity and self-reported disability (RMDQ). The validity of the main outcome measure employed to power the study (an estimated MCID in the RMDQ of 4) is open to debate. Various change scores have been reported for the MCID of the RMDQ ranging from 38% (Lauridsen, Hartvigsen et al. 2006) to 10 to15% (Grotle, Brox et al. 2004); a change score of 5 points has also been suggested (Stratford, Binkley et al. 1998). The change score is dependent upon the population under study, whereby acute populations have been shown to require a larger MCID value than chronic patients (van der Roer, Ostelo et al. 2006). A recent study investigating the MCID for pain and disability in 1349 patients with sub acute and chronic LBP patients reported that the MCID ranged from 2.5 to 6.8 points in those with baseline scores below 10 points, and from 5.5 to 13.8 in those baseline scores >15 points (Kovacs, Abraira et al. 2007). Since this research was investigating an acute LBP population it was estimated that the mean baseline RMDQ score would be relatively high (10 to 14) (Stratford, Binkley et al. 1998; Kovacs, Abraira et al. 2007). Taking into account that a 30% change threshold score has recently been proposed as a meaningful change score for the RMDQ (Ostelo, Deyo et al. 2008) the MCID was conservatively set as a score of 4. It is not known whether a smaller effect size (and therefore a larger patient population) would have resulted in a different outcome.

The choice of disability and activity limitation as the primary outcome measure may also be a factor in the non-significant association. The systematic review (Chapter IV) identified little evidence for a positive association between activity and measures of pain disability within LBP populations A recent study also found that self-reported disability correlated poorly with performance-based assessments of disability in an acute LBP population (Wand, Chiffelle et al. 2010). Symptom distribution, physical well being, and pain intensity correlated with the specific performance-based measures, and most noticeably the subject's levels of distress, depression and anxiety were also significantly correlated. Potential associations between psychological measures and activity were also reported in a recent study which found that depressive symptoms predicted upright time ($p < 0.05$) in individuals with chronic LBP (Ryan, Gray et al. 2010). A cross-sectional study within a chronic LBP population reported a moderate association between self-reported and objectively assessed activity levels ($p < 0.01$) (Huijnen, Verbunt et al. 2010). Importantly, the discrepancy between the two was significantly and negatively related to depression ($p = 0.01$), indicating that patients who had higher levels of depression judged their own activity level to be relatively low compared to their objectively assessed activity level (Huijnen, Verbunt et al. 2010). The levels of depression in the current study were relatively low (as measured by the GHQ-12 questionnaire) which may represent a factor in the lack of association between activity and disability. Therefore investigations of the potential associations between activity and a range of relevant psychological outcome measures including depression, self-efficacy, and fear avoidance are warranted to assess whether activity interacts in the disablement process via such mechanisms (Verbrugge and Jette 1994).

8.6 Use of activity as an outcome measure

Objective measures of PA are being increasingly employed as outcome measures in LBP research (De Jong, Vlaeyen et al. 2005; McDonough, Liddle et al. 2008). The results of this research and the systematic review indicate that activity represents a different paradigm to disability or pain in LBP populations. Therefore the use of such measures represents a useful addition to the array of outcome measures commonly employed in prospective LBP research (Bombardier 2000). Recent research also demonstrates that the responsiveness of LBP outcome variables is dependent upon the observed levels of activity limitation (Hall, Maher et al. 2010). Therefore PA measures may potentially identify sub-groups of patients for whom targeted interventions are more appropriate. As such research evolves the construct of PA and its role in the disablement process may become more apparent.

8.7 Generalisability of findings

International guidelines for LBP show some differences between countries (Arnau, Vallano et al. 2006); however PA prescription and advice remains a consistent feature across all guidelines. Therefore, although advice regarding activity and its use in primary care management of LBP has been shown to vary both across and within professional groups (Liddle, Gracey et al. 2007), it can be presumed that this variation is reasonably consistent. The high activity levels of participants in the current study, coupled with the relatively small number off work with their LBP, mean that the results may not relate to participants with lower levels of activity, and in particular if they were off work receiving compensation (McIntosh, Frank et al. 2000; McGuirk and Bogduk 2007). Further research is required on how activity and psychological factors affect various LBP populations across countries with differing compensation schemes.

It must also be acknowledged that this specific cohort, collected from physiotherapy practices, may differ in its activity levels, its view of activity, and the advice it was given regarding activity, when compared to all other community dwelling populations with acute LBP. Therefore the generalisability of these results requires comparison to other study groups investigating activity levels within primary care LBP cohorts.

The rationale for the requirement that all patients be attending a physiotherapist to be included in the study was to specifically study a population that has reached a clinical intervention threshold. Although recommendations exist for evidence based management of acute LBP (Ferguson, Brownlee et al. 2008; Bach and Holten 2009), research demonstrates that there is much variability in the primary care management of LBP (Fullen, Baxter et al. 2009), in that not all primary care health practitioners adhere to current best practice guidelines. Physiotherapy is a primary health care service within New Zealand does not require a medical practitioner's referral, and as such may represent a different population to those countries where referral to physiotherapy is required, as the patient characteristics may differ. The threshold was set at physiotherapy intervention to focus the research and generalisability of the research findings to this specific population. It is likely that the populations of patients that present to physiotherapy in New Zealand are comparable to other countries where physiotherapy is available as a first line service.

8.8 Limitations and future research directions

The current choice of RT3 triaxial monitor represented a pragmatic choice, with inherent drawbacks in that specified cut-off values for activity intensity have not been developed, and, unlike other activity monitors employed in LBP research, the monitor does not provide a direct measure of various activities including standing, walking, and lying (Ryan, Grant et al. 2008; Ryan, Gray et al. 2008) and (as discussed in Chapter III) has poor inter-rater reliability and utility issues for field use and provides a non-standardised measurement of PA. Also, the monitors were tested prior to field use, but underwent calibration with a mechanical shaker prior to study commencement, however, repetitive testing between each session of monitoring were not performed. Therefore, it is not known to what extent the measurement properties of the monitors changed over time and the potential impact of this on each individual's recorded activity over the eight weeks. The monitors were used by more than one subject during the trial, and it was not possible to re-calibrate the monitors (a process which requires the monitors to be returned to the manufacturer). This is an acknowledged weakness of activity monitors for field use (Godfrey, Conway et al. 2008). The units of activity employed in this research (RT3 VM/hr/wk), although extensively employed in field research as a measure of activity, has not been fully investigated for validity and responsiveness to change in free living research, an essential component of an activity measure (Warren, Ekelund et al 2010). However, there is no acknowledged and standardised field research protocol for accelerometry use, and few instruments have been evaluated for their ability to reliability evaluate change in activity over time, which remains a weakness of PA measures within populations with disability (Cervantes and Porretta 2010). It is also recognised that within each population the various dimensions of activity of interest will vary; therefore the focus of measurement should be tailored to the population of interest and the research question, as well as representing a compromise between costs, validity, and feasibility (Warren, Ekelund et al. 2010). The increasing use of activity monitors which are able to better capture the various dimensions of free living activity potentially offers a solution to many of these issues (Dorminy, Choi et al. 2008).

This study did not look at the behavioural adaptations to LBP, and the reasons why some participants increased or decreased activity over the two monitoring periods. Issues such as back pain beliefs (Goubert, Crombez et al. 2003) or the patient's beliefs about PA during the episode of LBP (Keen, Dowell et al. 1999) were not investigated, which might have helped to explain the non-significant associations found between activity and LBP outcomes. This research did not assess or investigate recognised models of adaptive behaviour to LBP

(Hasenbring et al., 1994) and/or the potential existence of avoiders and confronters of PA within this acute LBP population (Crombez et al., 1998). Such adaptive responses may represent an important sub-grouping within LBP populations (Severeijns, Vlaeyen et al. 2001). Further research should investigate for such behavioural responses within acute LBP cohorts, and interactions between activity and LBP outcomes.

The physiotherapy intervention that the patient received was not recorded, and therefore it is not clear how this might have influenced the patient's activity and recovery; despite this, it was presumed that all therapists were adhering to PA guidelines in respect to the advice given to patients. However, research suggests that advice regarding PA is not standardised (Liddle, Baxter et al. 2009) and there are also differences in the assessment process of LBP patients (Kent, Keating et al. 2009) and LBP outcomes employed within primary care management of LBP in New Zealand (Copeland, Taylor et al. 2008). Pragmatically, inclusion of other co-variates in the model (such as physiotherapy treatment) would also have required more subjects for the regression analysis used here. However, it is acknowledged that type of treatment, assessment, and advice given could potentially have influenced the outcomes of patients; although it is unknown whether this would have altered PA levels and therefore acted as a potential confounder. Therefore, further research is required to investigate whether specific guideline driven therapeutic interventions employing standardised assessment and outcome measures have a greater effect on a patient's activities during an episode of acute LBP.

8.9 Deconditioning model of low back pain re-examined

The lack of an observed association between LBP disability and activity levels at 3 months and 1 year do not support the role of deconditioning in chronic LBP and further supports recent research which has questioned its role in this population group (Bousema, Verbunt et al. 2007; Smeets and Wittink 2007; van Weering, Vollenbroek-Hutten et al. 2009). It is also acknowledged that the current population was relatively young (mean age 37 years), active, and predominantly working, and thus the generalisability of these results to other LBP populations requires further study. It maybe that this model of deconditioning is seen in patients with lower levels of activity or fitness at baseline, although there is little research to either confirm or refute this suggestion. The lack of an observed change in activity over the three time points, and the finding that activity was not a predictor of disability, calls into question how activity relates to the observed changes in muscle recruitment (van der Hulst,

Vollenbroek-Hutten et al. 2010), proprioception (Van Dieën, Selen et al. 2003; Hammill, Beazell et al. 2008), and decreases in muscle strength and endurance, and alterations in gait parameters, which are observed in patients with chronic LBP (Lee 2002; Mok, Brauer et al. 2004; Kjaer, Bendix et al. 2007). Potentially the link between these observed changes and LBP chronicity may be mediated by other factors. Other studies show predictive associations between performance-based activity measures and psychological measures including depression and kinesiophobia (Di Iorio, Abate et al. 2007; Schiphorst Preuper, Reneman et al. 2008), and correlations between psychological distress and activity levels (Ryan, Gray et al. 2010). Thus, physical alterations observed in LBP populations may be linked to such symptoms. Research shows links between LBP and emotional state and psychological well being (Abbott, Tyni-Lenné et al. 2010; Yoshino, Okamoto et al. 2010). Thus further research should explore the potential interactions between psychological and behavioural factors, and the observed alterations in muscle function and activity to investigate for potential moderating or mediating interactions within LBP populations.

8.10 Activity advice for low back pain reviewed

The use of activity as a treatment choice was not specifically addressed in this research; thus, although recorded activity levels did not predict functional disability within this cohort, it should be recognised that activity was not employed as a prescribed treatment approach and/or specifically targeted as an intervention. Research has recently targeted walking as a PA intervention for patients with LBP (Hurley, O'Donoghue et al. 2009; McDonough, Tully et al. 2010), although as yet there is little evidence for a positive role for increasing activity via a walking programme for LBP (Hendrick, Te Wake et al. 2010). A recent study investigated the potential interaction between structured motor re-training exercise in comparison to general walking on cortical re-organisation within a chronic LBP population (Tsao, Galea et al. 2010). Results found that cortical re-organisation to a more “normal” area within the brain was enhanced by targeted exercise rather than more general PA advice; however long term outcomes were not investigated. Results from this study, which found that a patient’s perception of a return to “normal” activities (and not necessarily a maintenance of a specific activity level) was associated with improved outcomes at 3 months would further support the prioritisation of structured exercise and activity, which focuses on the patient’s specific impairments (Macedo, Maher et al. 2009) and addresses potential behavioural and/or psychological issues relating to their LBP. However, it might be argued that those who maintain their activity levels have added health benefits and psychological well being and are

thus better able to cope with LBP; thus a combination of both approaches would seem to be prudent. The results of this study indicate that further research is required to elucidate the long-term associations between activity and LBP.

8.11 Conclusions

The research in this thesis was directed towards examining the temporal associations between activity and levels of disability within an acute LBP population over a period of 1 year. Although the measurement of PA in free living is problematic, the current research employed a range of validated measures to fully capture the various dimensions of PA. The results of the main study found no predictive association between either activity or change in activity and levels of pain, disability or chronicity at 3 months and 1 year. The results highlight the potential complexity in the association between activity and LBP disability, and the possible mediating effects of psychological variables to this relationship. These results also question the assumption that activity levels change as symptoms resolve from an episode of acute LBP, and also the potential role that physical activity plays in LBP recovery.

CHAPTER IX

Clinical Implications and Future Research Directions

9 Clinical implications and future research directions

Although this research found no predictive association between activity and LBP outcomes the results also highlight the complexity of such associations and that further exploration of the varied dimensions of PA within a range of LBP populations is warranted. Such research should include pedometer and questionnaire based assessment that would allow large scale evaluation within LBP populations, as well as evaluation of psychological and behavioural factors to investigate potential mediating effects of these variables on the association between activity and LBP. This research should also be targeted at patients who are at higher risk for chronicity (Kent and Keating 2008; Gurcay, Bal et al. 2009) based upon examination findings and the use of screening questionnaires (Hayden, Chou et al. 2009). Research should also focus on both quantitative and descriptively richer qualitative research that would allow a deeper exploration of the potential associations between activity and outcomes in LBP. Behavioural and psychological issues, including barriers to PA uptake and patient views around activity and LBP, could be better investigated to see whether targeted interventions within sub-groupings of LBP can achieve better long term outcomes.

9.1 Clinical implications for management and advice for patients

Results from the main study question the widely held view of the positive role of activity in recovery from acute LBP, and also the assumption that activity levels are diminished during an episode of LBP and then resolve as symptoms improve. These findings further support the results of the systematic review, (Chapter IV), which also found no significant association either cross-sectionally or longitudinally between a range of LBP outcome measures and measures of PA.

The finding that a return to full ‘normal’ activities rather than a change in activity was the important factor in functional disability at 3 months is an important outcome for clinicians and researchers to consider. It suggests that it is not the absolute amount of activity that is important in recovery, but rather the patient’s perception of the ease or difficulty in certain activities during an episode of LBP: these are specific to each patient. Thus it may be that achievement of an absolute level of activity is not the most important factor in achieving a

certain LBP outcome, but rather whether participants reach or maintain a level of activity with which they are happy and or they consider “normal”.

Based upon these results, an activity focus in the management and from LBP should primarily be informed by identifying those activities which the patient is having difficulty completing and/or which they consider they are unable to do normally. Thus the focus for management should include identifying barriers to restoration of “normal” activities including fear avoidance beliefs, and development of strategies and targeting treatment to enable the patient to return to what they consider ‘normal’ activities. These results also reinforce the requirement that this focus should be a relatively early goal in rehabilitation process, and should be continually monitored throughout the treatment. Therefore the use of both outcome measures and screening tools to identify potentially at risk patients is supported by these research results.

9.2 Further questions

Although clinical guidelines advocate exercise and activity in the management of NSLBP, the link between levels of PA and outcomes is unclear. Further research is required to identify and clarify the reasons for patients not achieving a return to ‘normal’ activities during an episode of LBP, as these patients had poorer outcomes at 3 months. Interestingly, a number of patients reported relatively high levels of disability but also a return to full ‘normal’ activities at baseline and thus, on an individual basis, a return to full ‘normal’ activities may not relate directly to either LBP disability or activity levels. This raises the possibility that these results may have identified behavioural responses to acute LBP similar to those reported in patients with chronic LBP (Hasenbring, Marienfeld et al. 1994). Recent research found that activity levels within a chronic LBP population were not influenced by pain or depression levels (Huijnen, Verbunt et al 2010). Thus the patient’s unique understanding of their condition and their particular behavioural response to pain and the consequent association with activity and disability is another interesting area for further research.

9.2.1 The role of the natural history of LBP on physical activity levels

Activity advice in the management of LBP shows favourable results; however reviews have highlighted the inconsistent recommendations adopted by primary care practitioners in LBP management (Liddle, Gracey et al. 2007; Liddle, Baxter et al. 2009). Therefore, further work needs to look at the effects of specific therapeutic interventions in conjunction with adaptation

of current guidelines for LBP on a patient's activities during an episode of LBP, and the consequent association with outcomes. Such research should also explore whether adoption of international guidelines by primary care practitioners provides an appropriate message with regards to movement and activity to alter the long term consequences of LBP.

The long term effects of an increase in a patient's activity to prevent future disability were not investigated here, but are allied to the additional health benefits of activity (Warburton, Nicol et al. 2006) identified in previous research (Hurwitz, Morgenstern et al. 2005). This would appear to be a reasonable and important goal, and particularly if early restoration of 'normal' activity can be achieved. Dose response associations between activity and a range of health outcomes are an on-going area of research (Bouchard 2001). Although no such dose response within this acute LBP population was found, the known health benefits of activity and the results support current recommendations for patients to maintain and restore their normal activity as part of the overall management of LBP. The finding that a patient's self- report of a return to full activities predicted functional disability at 3 months suggests that a focus on activity normalisation, rather than increasing activity, during an episode of acute back pain may offer the best opportunity for success in improving patient outcomes. These findings highlight the potential importance of the patient perceptions of activity and also the complex associations between activity and disability in LBP populations.

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APPENDIX

Memorandum

To: Professor Dave Baxter

Cc: Paul Hendrick, Meredith Perry

From: Dr Gill Johnson

Date: 7/03/07

Re: Re **Application Number 06/02 –The 8-week test-retest and utility of the RT3 accelerometer under free-living conditions.**

The Physiotherapy School Ethics committee has reviewed the final amendments made to the Information Sheet and is satisfied with the explanation regarding strength and flexibility in the 7-Day Questionnaire.

As a result of these considerations the current status of your proposal is: **Approved.**

NGĀI TAHU RESEARCH CONSULTATION COMMITTEE
TE KOMITI RAKAHAU KI KĀI TAHU

10/07/2007 - 27
Thursday, 12 July 2007

Professor David D A Baxter
School of Physiotherapy
Dunedin

Tēnā koe Professor Baxter

Title: A feasibility study to investigate the stability and utility of the RT3 accelerometer as a measure of activity over time in people with acute low back pain.

The Ngāi Tahu Research Consultation Committee (The Committee) met on Tuesday, 10 July 2007 to discuss your research proposition.

The Committee considers the research to be of importance to Māori health.

The Committee acknowledges that the researchers have identified Māori as being represented in the study and have given consideration to the cultural needs of participants.

The Committee strongly encourage that researchers collect ethnicity data as part of the project and recommend the use of the Census question on ethnicity.

The Committee advises that Māori are involved in work that may involve lower back pain to a greater degree, such as shearing and heavy farm work.

The Committee suggests dissemination of the research findings to relevant Māori health organisations.

The Committee would value a copy of the research findings.

Nāhaku noa, nā

Mark Brunton
Kaitakawaenga Rangahau Māori
Facilitator Research Māori
Research Division
Te Whare Wānanga o Otāgo
Ph: +64 3 479 8738
email: mark.brunton@otago.ac.nz
Web: www.otago.ac.nz

The 8-week test-retest reliability and utility of the RT3 accelerometer under free-living conditions

INFORMATION SHEET FOR PARTICIPANTS

Thank you for showing an interest in this project. Please read this information sheet carefully before deciding whether or not to participate. If you decide to participate we thank you. If you decide not to take part there will be no disadvantage to you of any kind and we thank you for considering our request.

What is the Aim of the Project?

This research is being carried out to ascertain the practical and technical issues of using an RT3 accelerometer to measure day to day physical activity in healthy human volunteers. The results of this study will be used in the design of a larger study which will investigate activity levels in patients with low back pain.

What Type of Participants are being sought?

A sample of 20 volunteers is being sought, aged 18 and over with no pre-existing medical conditions which limit their "normal" physical activity levels and walking ability.
Exclusion criteria: (1) Ability to remember to wear the RT3 daily, and to record their daily activities. (2) Participants with any history of current or past medical problems which prevents them from undertaking their usual day-to-day activities. (3) Inability to walk independently within the home and outside.

What will Participants be Asked to Do?

Should you agree to take part in this project, you will attend a session with the Research Assistant (RA) who will explain the procedure and instruct you on how to wear the RT3 accelerometer and also on filling in the daily activity log. The following measurements will then be taken or recorded: weight, height, age, occupation and gender. The RT3 will be attached to the waist belt in the centre of the lower back and switched on to start measuring and recording activity data. You will be required to wear the RT3 accelerometer for a period

of 1 week. The RT3 Tri-axial Research Tracker is designed as a complete activity recording and measurement system for clinical and research applications. The RT3 is the size of a pager and is worn on the waist. It is completely safe to use with all other electrical equipment that you may wear or operate e.g. hearing aids, pacemakers.

You will be required to wear the RT3 during waking hours (except when performing activities which might cause it to become wet, such as bathing or swimming) for 7 consecutive days, during which time you should maintain your typical weekly schedules. The RT3 will be taken off when in bed. You will also be asked to keep a daily log of activity whilst wearing the RT3 which will require you to complete a log recording your primary activity at hourly intervals. The RA will phone twice in the 7 day period to ensure that you are remembering to wear the RT3 and to record activities in the daily log. You may phone the RA at any time with any queries.

The RA will revisit you after 7 days, remove the RT3, collect the daily activity log and request that you complete a 7-day recall questionnaire administered by the RA and a utility questionnaire. The 7-day recall questionnaire asks you to recall the activities that you have performed over the past 7 days, and the utility questionnaire asks about problems you may have encountered with the RT3 accelerometer. You will be required to repeat this same procedure 4 and 8 weeks later.

The research processes described above should cause no harm or discomfort to any of the participants. Please be aware that you may decide not to take part in the project without any disadvantage to yourself of any kind.

Can Participants Change their Mind and Withdraw from the Project?

You may withdraw from participation in the project at any time and without any disadvantage to yourself of any kind.

What Data or Information will be Collected and What Use will be Made of it?

The following measurements will be taken or recorded: weight, height, age, occupation and gender. Information collected from physical activity monitors will be compared with information collected from the activity diaries and 7 day activity questionnaire.

The results of the project may be published and will be available in the library but every attempt will be made to preserve my anonymity.

You are most welcome to request a copy of the results of the project should you wish.

What if Participants have any Questions?

If you have any questions about our project, either now or in the future, please feel free to contact either:-

Paul Hendrick or ***Meredith Perry***

Department of Physiotherapy
Dunedin
Telephone Number: 03 479 5428
Email:paul.hendrick@otago.ac.nz

Department of Physiotherapy
Wellington
Telephone Number: 04 460 9808
meredith.perry@otago.ac.nz

Personal Information Sheet

To be filled out on day one of project participation

1. Name:_____

2. Date of Birth:_____

3. Address:_____
   _____
   _____
   _____

4. Gender:*Please circle* Male Female

5. Phone number: Home: Work: Mobile:

6. Occupation:

7. Would you regard your occupation to be more *Please circle one*

   manual or sedentary

8. What are the days you work normally?

9. On average how many hours a week would you work?

10. When thinking about physical activity over an average week, would you consider yourself to be *Please circle one*

    Not active Mildly active Moderately active Heavily active

11. On average how many days a week would you participate in regular sport? E.g. walking, running, gym, rugby, tennis.

12. Would you consider that activity to be *Please circle one*

Light Moderate Heavy

Thank you. The rest of the form will be completed by the Research assistant.

Height: cm

Weight:

Date:	**Visit 1**	**Visit 2**	**Visit 3**
kg			

Name: **Date:**

Accelerometer Utility Questionnaire

We need a measure of physical activity that is user-friendly for the person being measured. As the accelerometer is a new method of measuring daily activity in the home we would like to find out from you how acceptable this method was for you.

Please answer the following questions by placing a mark on the line that best represents what you think

1. Do you think wearing the accelerometer every day for 7 days was an acceptable method to measure your daily activity?

   _____

   Not acceptable *Very acceptable*

2. Was it easy for you to remember to wear the accelerometer every day?

   _____

   Difficult to remember *No problem*

3. How much did wearing the accelerometer every day interfere with your daily routine?

   _____

   Interfered greatly *Did not interfere at all*

4. How annoying was it for you to wear the accelerometer every day?

   _____

   Most annoying *Not annoying at all*

Please tick the box that best represents your answer to the question asked.

5. Would you mind wearing the accelerometer again as part of a research project?

   Yes ☐ No ☐ Maybe ☐

6. Do you think that for the person being tested the accelerometer is a "user-friendly" method of measuring daily activity?

   Yes ☐ No ☐ Maybe ☐

7. Please write below in the space provided any comments you have about wearing the accelerometer that you think we, as the researchers, ought to know.

_____

_____

_____

_____

_____

_____

_____

_____

Thank you for completing this questionnaire.

Activity Monitor Reliability Re Test Protocol

Before session.

Research Assistant walks up stairs and down to check monitor is working. This information is downloaded in to the laptop. **Time:10min**

With Participant

1. Welcome

Explanation of the project:

What this project aims to do

a) what the RT3 is and how it works see next page

.Discuss effects of:

b) dropping, water and pressing of buttons.

c) advice regarding wearing of monitor for all activities

d) and to put the monitor in a prominent position to minimise forgetfulness see next page

Forms to fill in:

a) The subject information sheet
b) The activity diary. Emphasize that it is to be filled out if possible hourly and with the activity done for the longest period of time in the hour.
c) The 7 day recall explanation. When it will be filled out.
d) What will happen today
e) Questions? **Time: 12min**

2. Gain signed consent. **Time: 2 min**

3. Discuss further arrangements

a) Determine when to call/email the subject once (twice) within the next 7days.
b) Make appointment for RT3 retrieval, collection of diary and 7 Day Recall
c) Questions? **Time: 5 min**

4. Data gathering

Fill in subject information sheet.

Take height and weight measurements, record in subject profile.

Time: 3 min

Load RT3. Attach to central lumbar spine to waistband on trousers or belt

Questions **Time: 3 min**

5 minute walk test setting marker at beginning and end **Time: 7 min**

5. Reconfirm next appointment

6. Questions Time: 5 min

Total Time with participant:	**37 min**
Total Time	**47mim**

Standardised Protocol of RT3 Explanation

Thank you being interested in this project. What we are hoping to do with this research is look at how reliable the RT3 is at measuring your activity over a week when compared to a trial four and eight weeks later. It is hoped that if the machines are found to be reasonably reliable and not cumbersome to wear that these machines could be used in further studies looking at people with various medical conditions.
What we are requiring from you, is to wear the machines for a week, reporting the activities you have been involved in and how much of an intrusion the machines have been to wear.

The RT3 is an accelerometer. This means that it measures the displacement of your body from a set point in three axes.

Therefore any time you move it will pick up some activity. The amount of activity is recorded for every minute and given a number value. This value is called an activity count. Activities which require bigger movements will be recorded as a greater number of counts.

It is very light weight. And easily attaches to your clothes.

<u>This is the Activity Diary.</u>

We would like you to fill in each hour what your main activity was for that hour. Such as if you spent 50 minutes at work and then 10 minutes driving home your main activity would be work painting.

Or 40 minutes running 10 minutes washing and then 10 minutes resting, your main activity would be running.

If you feel it is really 50:50 then put both activities down.

1. Try to remember to wear the RT3 during all awake hours.
2. Fill in the main activity for each hour that you have worn the RT3.
3. Remember to remove the RT3 when engaging in water activities and when going to bed.
4. Put the RT3 beside your bed to help you to remember to put back on in the mornings.
5. Please highlight the days on which you did not work with an asterix by the date

7 Day Recall.

When you give me back the monitor I will collect from you the Activity Diary, ask you to fill in a form about how you found wearing the monitor and finally a series of questions about your activity over the week.

Today what we will do is get you read and sign the consent form. Take your weight and height measurement and load these into the RT3 machine. Ask you to complete a five minute walk test. I will then discuss when you would like me to ring or email you and finally make an appointment to collect the monitor from you.

NGĀI TAHU RESEARCH CONSULTATION COMMITTE
TE KOMITI RAKAHAU KI KĀI TAHU

13/11/2007 - 12
Wednesday, 14 November 2007

Mr Paul Hendrick
School of Physiotherapy
Dunedin

Tēnā koe Mr Hendrick

Title: Investigating the relationship between physical activity levels and change in disability over time in a low back pain population

The Ngāi Tahu Research Consultation Committee (The Committee) met on Tuesday, 13 November 2007 to discuss your research proposition.

The Committee considers the research to be of importance to Māori health.

The Committee notes that the researchers have identified that Māori may be participants in the study and that the researchers intend to collect ethnicity information, as such the Committee strongly encourage that researchers use the Census question on ethnicity.

The Committee advise that Māori prevalence to lower back pain is likely, given the types of work they are engaged in.

The Committee commends the researchers on the intention to consult further should initial indications suggest there is an implication for specific ethnic groups.

The Committee suggests dissemination of the research findings to relevant Māori health organisations.

The Committee would also value a copy of the research findings.

The recommendations and suggestions above are provided on your proposal submitted through the consultation website process. These recommendations and suggestions do not necessarily relate to ethical issues with the research, including methodology. Other committees may also provide feedback in these areas.

Nāhaku noa, nā

Mark Brunton
Kaitakawaenga Rangahau Māori
Facilitator Research Māori
Research Division
Te Whare Wānanga o Otāgo
Ph: +64 3 479 8738
email: mark.brunton@otago.ac.nz
Web: www.otago.ac.nz

The Ngāi Tahu Research Consultation Committee has membership from:

Te Rūnanga o Ōtākou Incorporated
Kāti Huirapa Rūnaka ki Puketeraki
Te Rūnanga o Moeraki

Ethics Approval

7 January 2008

Paul HendrickPhysiotherapySchool of PhysiotherapyPO Box 56, University of OtagoDunedin

Dear Paul,

Project Key: LRS/07/11/043

Full Title: Investigating the relationship between physical activity levels and changes in disability over time in low back pain population.

Investigators: Paul Hendrick, Professor David Baxter, Dr. Stephan Milosavljevic, Dr. Leigh Hale, Dr. Melanie Bell.

Localities: School of Physiotherapy, Participants' own home work or social environment of choice.

The above study has been given ethical approval by the **Lower South Regional** Ethics Committee. A list of members of this committee is attached.

Approved Documents

Information sheet and consent form version no. 2 dated 28 Nov 2007

Certification

The Committee is satisfied that this study is not being conducted principally for the benefit of the manufacturer or distributor of the medicine or item in respect of which the trial is being carried out.

Accreditation

The Committee involved in the approval of this study is accredited by the Health Research Council and is constituted and operates in accordance with the Operational Standard for Ethics Committees, April 2006.

Progress Reports

The study is approved until **31 December 2009**. The Committee will review the approved application annually and notify the Principal Investigator if it withdraws approval. It is the Principal Investigator's responsibility to forward a progress report covering all sites prior to ethical review of the project in **7 January 2009**. The report form is available on http://www.newhealth.govt.nz/ethicscommittees. Please note that failure to provide a progress report may result in the withdrawal of ethical approval. A final report is also required at the conclusion of the study.

Requirements for SAE Reporting

The Principal Investigator will inform the Committee as soon as possible of the following:

- Any related study in another country that has stopped due to serious or unexpected adverse events
- withdrawal from the market for any reason
- all serious adverse events occurring during the study in New Zealand which result in the investigator breaking the blinding code at the time of the SAE or which result in hospitalisation or death.
- all serious adverse events occurring during the study worldwide which are considered related to the study medicine. Where there is a data safety monitoring board in place, serious adverse events occurring outside New Zealand may be reported quarterly.

All SAE reports must be signed by the Principal Investigator and include a comment on whether he/she considers there are any ethical issues relating to this study continuing due to this adverse event. It is assumed by signing the report, the Principal Investigator has undertaken to ensure that all New Zealand investigators are made aware of the event.

Amendments

All amendments to the study must be advised to the Committee prior to their implementation, except in the case where immediate implementation is required for reasons of safety. In such cases the Committee must be notified as soon as possible of the change.

Please quote the above ethics committee reference number in all correspondence.

The Principal Investigator is responsible for advising any other study sites of approvals and all other correspondence with the Ethics Committee.

It should be noted that Ethics Committee approval does not imply any resource commitment or administrative facilitation by any healthcare provider within whose

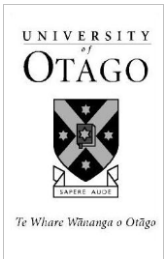
facility the research is to be carried out. Where applicable, authority for this must be obtained separately from the appropriate manager within the organisation.

Yours Sincerely,

Riria Tautau-Grant
Ethics Committee Administrator
Lower South Regional Ethics Committee
email: riria_tautau-grant@moh.govt.nz

Lower South Regional Ethics Committee members

Mrs Jennifer Beck - Chairperson	Lawyer
Dr Philip White - Deputy Chairperson	Health Practitioner
Mr Kenneth Copland	Community Representative
Mrs Sandra Elkin	Ethicist
Dr Nikki Kerruish	Health Practitioner
Mrs Gwen Neave	Community Representative
Dr Alan Payne	Researcher
Dr Clare Robertson	Biostatistician
Dr Khyla Russell	Community Representative
Dr. Rosemary Beresford	Pharmacist/ Pharmacologist
Karen Goffe	Community Representative (Jan 2007)
Dr. Sarah Derrett	Researcher (Jan 2007)



Monitoring physical activity in people with low back pain.

Information Sheet for Participants with Low Back Pain

Thank you for showing an interest in this profject. Please read this information sheet carefully before deciding whether or not to participate. If you decide not to take part either at this point in time or during the project, there will be no disadvantage to you of any kind.

What is the Aim of the Project?

This research is being carried out to investigate physical activity levels in people with low back pain (LBP) and to see how these activity levels are associated with functional recovery. We will measure you're activity with an activity monitor called an RT3. The RT3 is the size of a pager and is secured within a holder and worn on the waist. It measures acceleration forces in three directions as you move throughout the day completing activities of daily living. It is completely safe to use with all other electrical equipment that you may wear or operate e.g. hearing aids, pacemakers, and it will not make your back pain any worse.

What Type of Participants are being sought?

We require 80 adult participants between the ages of 18-65 years, who live in the Dunedin area and who have developed lower back pain in the last 6 weeks', but who have not had lower back pain for three months prior to this.

To be eligible to participate in this study you should be able to speak English and to remember to wear the RT3 monitor every day and to complete a daily activity log. We will discuss your back pain with you but if we think that it is more complex than simple mechanical low back pain then, for your own safety, you will not be eligible to participate in our study and we will strongly recommend that you contact your health practitioner.

What will Participants be Asked to Do?

Should you agree to take part in this project, you will attend a session with the principal investigator, Paul Hendrick, at your convenience at a location suitable for you within six weeks of the onset of your back pain. At this session, you will be asked to provide written consent and given the opportunity to ask any further questions. Paul will measure your weight and height and record your age, gender occupation and ethnicity. The RT3 monitor will then be placed over your right hip in a harness and set to start recording. You will also be given an activity log and instructed to fill in the main activities(s) that you do for each hour over seven days. You will also be required to complete five questionnaires relating to your back pain symptoms, general health and activity levels prior to the onset of back pain. This first session will take approximately 40 minutes.

You will be required to wear the RT3 activity monitor during the waking hours for seven days (except when performing activities that might cause the RT3 to become wet, such as bathing or swimming). Paul will contact you twice during the week by telephone to find out if you are experiencing any difficulties with wearing the RT3. If you have any questions or experience any problems with the RT3 monitor during the seven days you are encouraged to contact Paul. At the end of the seven days Paul will arrange to meet you and collect the monitor at a time and location suitable for you. You will be required to fill in a questionnaire that asks you to recall your activities over the last seven days. This session will take approximately 20 minutes. You will be required repeat the above procedure at twelve weeks from the first activity monitoring period.

The research processes described above should cause no harm or discomfort to any of the participants. The total time commitment over the twelve weeks is approximately 2.0 hours. At 1 year from the first activity monitoring point you will be sent the five questionnaires to complete relating to your back pain symptoms, including a questionnaire about your current activity levels in a stamp addressed envelope to return to Paul.

Can Participants Change their Mind and Withdraw from the Project?

You may withdraw from participation in the project at any time and without any disadvantage to yourself of any kind and withdrawing from the project will not impact on treatment you are receiving form your health practitioner.

What Data or Information will be Collected and What Use will be Made of it?

The following data will be recorded: weight, height, age, occupation, gender and ethnicity. Information collected from physical activity monitors will be compared with information collected from the activity log and the activity questionnaire.

The data from the five questionnaires asking about your symptoms, any difficulty completing work or

home based tasks due to the back pain and usual levels of activity will be compared to the level of activity recorded by the activity questionnaire and the RT3 measure.

The results of the project may be published and will be available in the library but every attempt will be made to preserve your anonymity. You are most welcome to request a copy of the results of the project should you wish.

All data collected will be securely stored in such a way that only the principle investigator and assistant will be able to gain access to it. At the end of the project any personal information will be destroyed immediately except that, as required by the University's research policy, any raw data on which the results of the project depend will be retained in secure storage for ten years, after which it will be destroyed. Reasonable precautions will be taken to protect and destroy data gathered by email. However, the security of electronically transmitted information cannot be guaranteed. Caution is advised in the electronic transmission of sensitive material.

Other people involved in the Project:

Prof David Baxter, Dr Stephan Milosavljevic, Dr Leigh Hale
School of Physiotherapy
University of Otago
PO Box 56
Dunedin
Phone: (03) 479 7460

Dr Melanie Bell
Adams Building, Health Sciences,
Dunedin School of Medicine
University of Otago
Dunedin
Phone: (03) 479 7201

What if Participants have any Questions?

If you have any questions about our project, either now or in the future, please feel free to contact:-

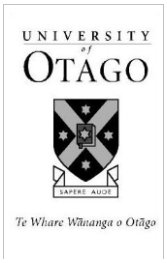
Paul Hendrick
School of Physiotherapy
University of Otago
PO Box 56
Dunedin
Phone: (03) 479 5428

Participant Rights

If you have any questions or concerns about your rights as a participant in this research study you can contact an independent health and disability advocate. This is a free service provided under the Health and Disability Commissioner Act. Local (03) 479 0265; Telephone: (NZ wide) 0800 555 050; Free Fax (NZ wide): 0800 2787 7678 (0800 2 SUPPORT); Email (NZ wide): advocacy@hdc.org.nz If there is a specific Māori issue/concern please contact Linda Grennell at 0800 37 77 66

In the unlikely event of a physical injury as a result of your participation in this study, you will be covered by the accident compensation legislation with its limitations. If you have any questions about ACC please feel free to ask the researcher for more information before you agree to take part in this trial

This study has been approved by the Lower South Regional Ethics Committee.



Monitoring physical activity in people with low back pain.

CONSENT FORM

I have read the Information Sheet concerning this project and understand what it is about. All my questions have been answered to my satisfaction. I understand that I am free to request further information at any stage.

I know that:-

1. my participation in the project is entirely voluntary;

2. I am free to withdraw from the project at any time without any disadvantage;

3. the data will be destroyed at the conclusion of the project but any raw data on which the results of the project depend will be retained in secure storage for five years, after which it will be destroyed;

4. the results of the project may be published and available in the library but every attempt will be made to preserve my anonymity.

5. I understand that reasonable precautions have been taken to protect data transmitted by email but that the security of the information cannot be guaranteed.

I agree to take part in this project.

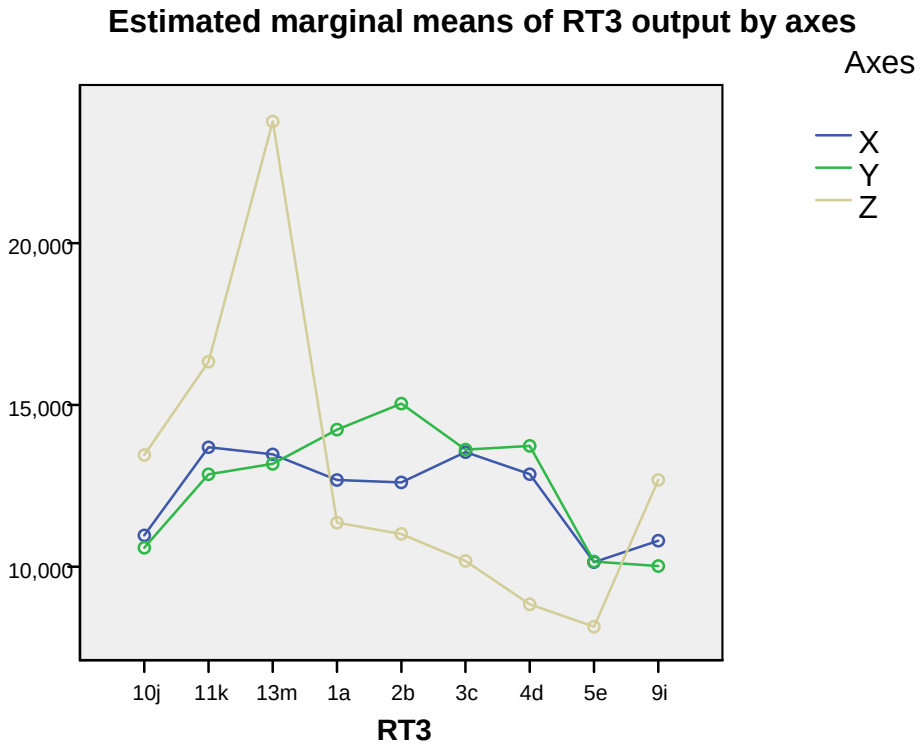
....

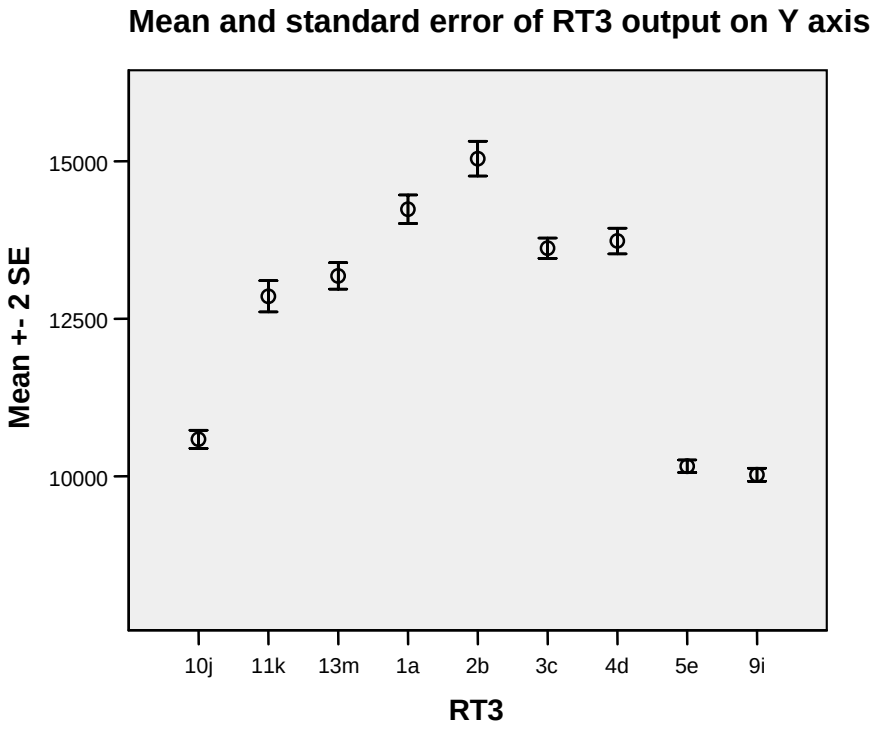
(Signature of participant) (Date)

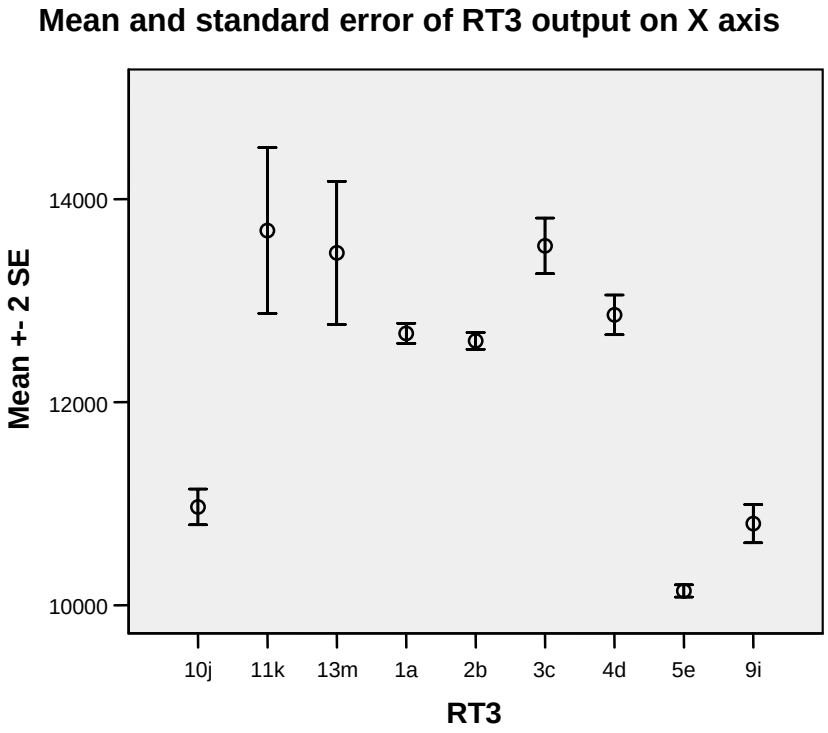
The on-going management of low back pain is a high priority research area for the School of Physiotherapy: please tick the box if you would be willing to be contacted in the future in research projects investigating long term outcomes in low back pain

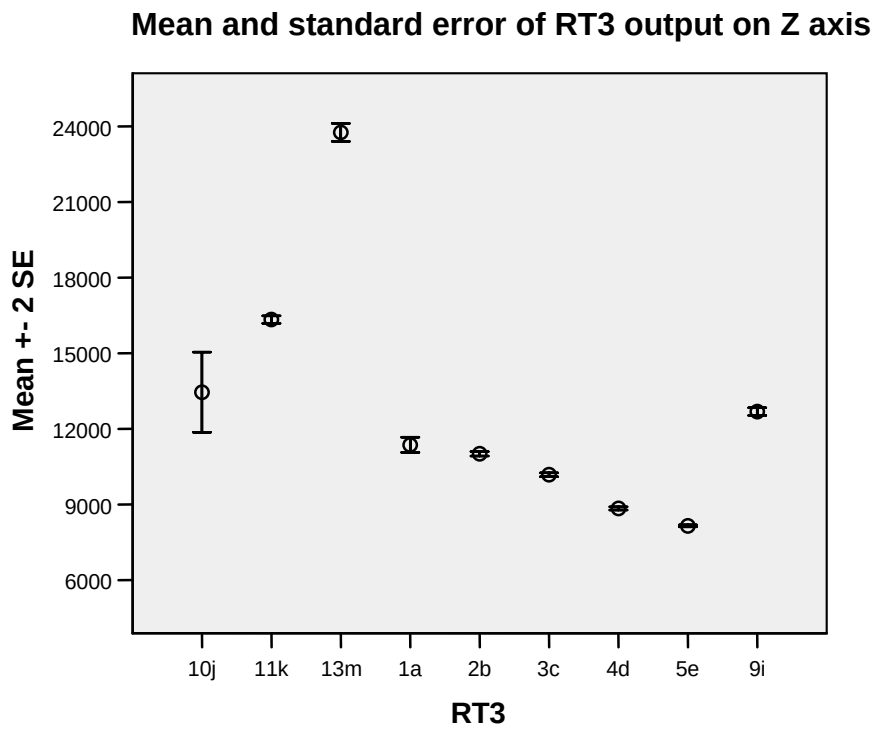
This study has been approved by the Lower South Regional Ethics Committee.

RT3 Pre-monitor testing data




Mean and standard error of RT3 output on Y axis
Mean +- 2 SE
15000
12500
10000
10j
11k
13m
1a
2b
3c
4d
5e
9i
RT3


Mean and standard error of RT3 output on X axis
Mean +- 2 SE
14000
12000
10000
10j
11k
13m
1a
2b
3c
4d
5e
9i
RT3


Mean and standard error of RT3 output on Z axis
Mean +- 2 SE
24000
21000
18000
15000
12000
9000
6000
10j
11k
13m
1a
2b
3c
4d
5e
9i
RT3

Activity Monitor Protocol

With Participant

1. Welcome

Explanation of the project:

What this project aims to do:

Patient to read information sheet

Questions **Time: 5mins**

Forms to fill in:

The subject information sheet

Discuss the activity diary with the participant.

Discuss:

The 7 day recall questionnaire – give an explanation of when it will be filled out at the end of the 7 days.

Explain what will happen today

Questions **Time: 12min**

2. Gain signed consent. Time: 2 min

3. Discuss further arrangements

Determine when to call/email the subject twice within the next 7days.

Make appointment for RT3 retrieval, collection of diary and 7 Day Recall

Questions **Time: 5 min**

4. Data gathering

Take height and weight measurements, record in subject profile.

Time: 3 min

Load RT3. Place RT3 in harness and attach to right hip

Questions **Time: 3 min**

5. Reconfirm next appointment

6. Questions **Time: 5 min**

Total Time with participant: 35 min

Standardised Protocol of RT3 Explanation

Thank you being interested in this project. What I am hoping to do with this research is to measure your activity with an RT3 activity monitor for 7 days. The RT3 is an accelerometer and this means that it measures the displacement of your body from a set point in three axes. Therefore any time you move it will pick up some activity. The amount of activity is recorded for every minute and given a number value. This value is called an activity count. Activities which require bigger movements will be recorded as a greater number of counts. It is very light weight and easily attaches to your clothes.

You will be required to wear the monitor attached to the side of your right hip during all waking hours for the next 7 days. You should remove the RT3 for any water based activities (e.g. bathing or showering) and at night in bed. If you remove the RT3 please try to remember to put the monitor in a prominent position to help you remember to put the monitor back on. If you need to remove the RT3 for any reason or forget to put the RT3 on, please note in the activity diary the time period and any reason for removal.

The RT3 monitor is reasonably resilient to being knocked, however you should try to not drop the monitor, which could cause it to become faulty. If you notice that monitor display on the RT3 stops flashing (show the participant the monitor display) I would ask you to contact me. Once I have started the RT3 you will not be able to stop or alter the monitoring by pressing any of the buttons on the monitor. The data from the RT3 can only be accessed by docking the RT3 to specialist software on this computer.

Do you have any questions about RT3 or the activity monitoring procedure?

<u>Activity Diary.</u>

I would also like you to fill in an activity diary over the next 7 days. This will require you to fill in each waking hour what your main activity was for that hour. So for example if you spent 50 minutes at work painting and then 10 minutes driving home your main activity would be noted as “work painting” in the diary. Or if for example you spent 40 minutes running, 10 minutes washing and then 10 minutes resting, your main activity would be noted as running in the diary.

If you feel there are two main activities for that hour then you can put both activities down in the diary. I would recommend that you fill in the activity diary at certain set points in the day,

for example meal times, as this will help you to remember to complete the activity diary. Please highlight the days on which you did not work with an asterix by the date

When you give me back the monitor at the end of the 7 days I will collect the activity diary and ask you a series of questions about your activities over the week. The information in the activity diary will help you to answer these questions.

Today what we will do is get you to read and sign the consent form and patient information sheet. I will then take your weight and height measurement and load these data into the RT3 machine. I will then discuss when you would like me to ring or email you and make an appointment to collect the monitor from you. I will then attach the RT3 to your right hip in a harness and start the machine.

Participant Screening Questionnaire

Name: **ID:** **Date:**

The following questions are designed to screen for any potential pathologies which may exclude you from taking part in this study

Please indicate if you are positive for any of the following:

- Features of cord or cauda equina syndrome: especially urinary retention, and or a difficulty to postpone urination, loss of sensation in the saddle region, pins and needles in both legs, or unsteadiness in gait
- A recent history of significant trauma affecting your lower back
- Unexplained weight loss
- A recent history of cancer
- Fever
- General ill health
- Intravenous drug use
- Steroid use
- Severe, unremitting night-time pain
- Pain that gets worse when you are lying down

Questionnaire adapted from ACC. (2003). *Best Practice Guidelines. New Zealand Acute Low Back Pain Guide. Guide to Assessing Psychosocial Yellow Flags in Acute Low Back Pain*. New Zealand: ACC.

Personal Information Sheet

To be filled out on day one of project participation

9. Name:_____

10. Date of Birth:_____

11. Address:_____
    _____
    _____
    _____

12. Gender: *Please circle* Male Female

13. Ethnicity_____

14. Phone number: Home: Work: Mobile:

15. Please give an alternative contact person (e.g. someone who would know your new address and phone number if you moved house):

    Name (first, last) _____

    Phone _____

16. Address (optional) :
    _____
    _____
    _____
    _____

17. Occupation _____

18. Would you regard your occupation to be more *Please circle one*

    manual or sedentary

19. What are the days you work normally? _____

12. On average how many hours a week would you work? _____

Thank you. The rest of the form will be completed by the Research assistant.

Height: **cm**

Weight:

Date:	**Visit 1**	**Visit 2**
kg		

Daily Activity log-book

Name: _____

Address: _____

_____

_____

Telephone number: _____

Email address: _____

Contact Details

Paul Hendrick **03 479 5428**

paul.hendrick@otago.ac.nz

Activity Log

This is an example page to show you how to fill out the Activity Diary.

1. Wear the RT3 during all awake hours.

2. Fill in the main activity for each hour.

3. Remember to remove the RT3 when engaging in water activities and when going to bed.

4. Put the RT3 beside your bed to help you to remember to put back on in the mornings.

5. Please highlight the days on which you did not work with an asterix by the date

Time	Date	Date	Date	Date	Date	Date	Date
0400	asleep	asleep	asleep	asleep	asleep	asleep	asleep
0500	asleep	asleep	asleep	asleep	asleep	asleep	asleep
0600	asleep	Washed Brkfast.	Washed Brkfast.	Swim	asleep	asleep	asleep
0700	Washed Brkfast.	Drove to work	Drove to work	Washed Brkfast.			
0800	Drove to work	Work sanding	Work sanding				
0900	Work painting	Work sanding	Work sanding				
1000	Work painting	Work sanding	Work sanding				
1100	Work painting	Work sanding	Work sanding				
1200	Work inspecting	Work painting	Work painting				
1300	Lunch/ walk	Work painting	Work painting				
1400	Work painting	Lunch/ walk	Lunch/ walk				
1500	Work painting	Work painting	Work invoicing				
1600	Work painting	Work painting	Work invoicing				
1700	Gym weights	run	Work invoicing				
1800	Gym weights	Watching TV	Work invoicing				
1900	Home/ dinner	Home/ dinner	Dinner				
2000	Watching TV		Dinner				
2100	Watching TV		Movies				
2200	Reading in bed		Movies				
2300	asleep		Movies				

Week One

Time	Date	Date	Date	Date	Date	Date	Date
0000							
0100							
0200							
0300							
0400							
0500							
0600							
0700							
0800							
0900							
1000							
1100							
1200							
1300							
1400							
1500							
1600							
1700							
1800							
1900							
2000							
2100							
2200							
2300							

Week Twelve

Time	Date	Date	Date	Date	Date	Date	Date
0000							
0100							
0200							
0300							
0400							
0500							
0600							
0700							
0800							
0900							
1000							
1100							
1200							
1300							
1400							
1500							
1600							
1700							
1800							
1900							
2000							
2100							
2200							
2300							

Simple Activity Questionnaire

Name: **ID:** **Date:**

Do you consider that you have returned to full “normal” activities since this current episode of low back pain?

Yes

No

Please circle your response.

Name: _____ ID: _____ Date: _____

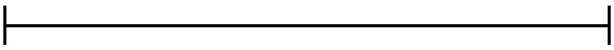
Baecke Physical Activity Questionnaire

		Investigator use only
1. What is your main occupation?		1-3-5
2. At work I sit:	never seldom sometimes often always	1-2-3-4-5
3. At work I stand:	never seldom sometimes often always	1-2-3-4-5
4. At work I walk:	never seldom sometimes often always	1-2-3-4-5
5. At work I lift heavy loads:	never seldom sometimes often always	1-2-3-4-5
6. After work I am tired:	very often often sometimes seldom never	5-4-3-2-1
7. At work I sweat:	very often often sometimes seldom never	5-4-3-2-1
8. In comparison with others of my own age, I think my work is physically:	much heavier heavier as heavy lighter much lighter	5-4-3-2-1
9. Do you play a sport?	Yes No	
If yes, which sport do you play most frequently? _____		
How many hours a week?	<1 1-2 2-3 3-4 >4	
How many months per year?	<1 1-3 4-6 7-9 >9	
If you play a second sport, which sport is it? _____		
How many hours a week?	<1 1-2 2-3 3-4 >4	
How many months per year?	<1 1-3 4-6 7-9 >9	
10. In comparison with others of my own age, I think my physical activity leisure time is:	much more more as much less much less	5-4-3-2-1
11. During leisure time I sweat:	very often often sometimes seldom never	5-4-3-2-1
12. During leisure time I play sport:	never seldom sometimes often always	1-2-3-4-5
13. During leisure time I watch television:	never seldom sometimes often always	1-2-3-4-5
14. During leisure time I walk:	never seldom sometimes often always	1-2-3-4-5
15. During leisure time I cycle:	never seldom sometimes often always	1-2-3-4-5
16. How many minutes do you walk and/or cycle per day to and from		
17. work, school and shopping?	<5 5-15 15-30 30-45 >45	1-2-3-4-5

Work Index = Sport Index = Leisure-time index =

Patient Name: _____ Date: _____

Visual Analog Scale (VAS)*



No pain

Pain as bad as it could possibly be

*A 10-cm baseline is recommended for VAS scales.
From: Acute Pain Management: Operative or Medical Procedures and Trauma, Clinical Practice Guideline No. 1. AHCPR Publication No. 92-0032; February 1992. Agency for Healthcare Research & Quality, Rockville, MD; pages 116-117.

Visual Analog Scale

NO PAIN _____ WORST PAIN

Directions: Ask the patient to indicate on the line where the pain is in relation to the two extremes. Measure from the left hand side to the mark.

From Stratton Hill C. Guidelines for Treatment of Cancer Pain: The Revised Pocket Edition of the Final Report of the Texas Cancer Council's Workgroup on Pain Control in Cancer Patients, 2nd Edition; pages 61-63. Copyright 1997, Texas Cancer Council. Reprinted with permission. www.texascancercouncil.org.

A7012-AS-1

Name: ID: Date:

FEAR AVOIDANCE BELIEFS QUESTIONNAIRE (FABQ)

Name: _____ Date: mm / dd / yy

Here are some of the things other patients have told us about their pain. For each statement please circle the number from 0 to 6 to indicate how much physical activities such as bending, lifting, walking or driving affect or would affect your back pain.

		Completely Disagree			Unsure			Completely Agree
1.	My pain was caused by physical activity	0	1	2	3	4	5	6
2.	Physical activity makes my pain worse.	0	1	2	3	4	5	6
3.	Physical activity might harm my back.	0	1	2	3	4	5	6
4.	I should not do physical activities which (might) make my pain worse.	0	1	2	3	4	5	6
5.	I cannot do physical activities which (might) make my pain worse.	0	1	2	3	4	5	6

The following statements are about how normal work affects or would affect your back pain.

		Completely Disagree			Unsure			Completely Agree
6.	My pain was caused by my work or by an accident at work.	0	1	2	3	4	5	6
7.	My work aggravated my pain.	0	1	2	3	4	5	6
8.	My work is too heavy for me.	0	1	2	3	4	5	6
9.	My work makes or would make my pain worse.	0	1	2	3	4	5	6
10.	My work might harm my back.	0	1	2	3	4	5	6
11.	I should not do my regular work with my present pain.	0	1	2	3	4	5	6
12.	I cannot do my normal work with my present pain	0	1	2	3	4	5	6
13.	I cannot do my normal work until my pain is treated.	0	1	2	3	4	5	6
14.	I do not think I will be back to my normal work within 3 months.	0	1	2	3	4	5	6
15.	I do not think that I will ever be able to go back to that work.	0	1	2	3	4	5	6

The Roland-Morris Disability Questionnaire

From: Roland MO, Morris RW. A study of the natural history of back pain. Part 1: Development of a reliable and sensitive measure of disability in low back pain. Spine 1983; 8: 141-144

This list contains sentences that people have used to describe themselves when they have back pain. When you read them, you may find that some stand out because they describe you today. As you read the list, think of yourself today. When you read a sentence that describes you today, put a tick against it. If the sentence does not describe you, then leave the space blank and go on to the next on. Remember; only tick the sentence if you are sure it describes you today.

Scoring the RDQ. The score is the total number of items checked – i.e. from a minimum of 0 to a maximum of 24.

1. I stay at home most of the time because of my back.

2. I change position frequently to try and get my back comfortable.

3. I walk more slowly than usual because of my back.

4. Because of my back I am not doing any of the jobs that I usually do around the house.

5. Because of my back, I use a handrail to get upstairs.

6. Because of my back, I lie down to rest more often.

7. Because of my back, I have to hold on to something to get out of an easy chair.

8. Because of my back, I try to get other people to do things for me.

9. I get dressed more slowly then usual because of my back.

10. I only stand for short periods of time because of my back.

11. Because of my back, I try not to bend or kneel down.

12. I find it difficult to get out of a chair because of my back.

13. My back is painful almost all the time.

14. I find it difficult to turn over in bed because of my back.

15. My appetite is not very good because of my back pain.

16. I have trouble putting on my socks (or stockings) because of the pain in my back.

17. I only walk short distances because of my back.

18. I sleep less well because of my back.

19. Because of my back pain, I get dressed with help from someone else.

20. I sit down for most of the day because of my back.

21. I avoid heavy jobs around the house because of my back.

22. Because of my back pain, I am more irritable and bad tempered with people than usual.

23. Because of my back, I go upstairs more slowly than usual.

24. I stay in bed most of the time because of my back.

Nordic Low back pain Questionnaire

Name: ID: Date:

Physical activity and low back pain 1 year review

Instructions: These questions relate to your back pain over the previous year. Please read and answer each question carefully. Do not take too long to answer the questions. However, it is important that you answer every question.

Please put a tick in the appropriate box | √ | for each question.

		During the last7 days	During last 12 months
1.	Do you consider your back pain to be	NOT APPLICABLE	persistent , chronic or ongoing | | resolved | |
2.	How many episodes of low back pain have you had?	0 | | 1 | | 2-4 | | 4+ | |	0 | | 1 | | 2-5 | | 6-10 | | More than 10 | |
3.	If working, how much time did you have to take off work due to the back pain?	None | | 3-5 days | | 1-2 days | | More than 5 days | |	None | | 4-6 months | | 1-4 weeks | | 1-3 months | | More than 6 months | |
4.	Since your episode of back pain 1 year ago have you had a new injury to your back that required a visit to any type of health professional?	NO | | YES | | What happened?	NO | | YES | | What happened?
5.	Did your injury require treatment? (Anti-inflammatory drugs, painkillers, physiotherapy, chiropractor, osteopath, surgery, hospital consultant, other?)	NO | | YES | | Namely _____	NO | | YES | | Namely _____

Name: **ID:** **Date:**

Accelerometer Utility Questionnaire

We need a measure of physical activity that is user-friendly for the person being measured. As the accelerometer is a new method of measuring daily activity in the home we would like to find out from you how acceptable this method was for you.

Please answer the following questions by circling the number that best represents what you think

8. Do you think wearing the accelerometer every day for 7 days was an acceptable method to measure your daily activity?

Not acceptable *Very acceptable*

1 2 3 4 5

9. Was it easy for you to remember to wear the accelerometer every day?

Difficult to remember *No problem*

1 2 3 4 5

10. How much did wearing the accelerometer every day interfere with your daily routine?

Interfered greatly *Did not interfere at all*

1 2 3 4 5

11. How annoying was it for you to wear the accelerometer every day?

Most annoying *Not annoying at all*

1 2 3 4 5

Please tick the box that best represents your answer to the question asked.

12. Would you mind wearing the accelerometer again as part of a research project?

Yes ☐ No ☐ Maybe ☐

13. Do you think that for the person being tested the accelerometer is a "user-friendly" method of measuring daily activity?

Yes ☐ No ☐ Maybe ☐

14. Please write below in the space provided any comments you have about wearing the accelerometer that you think we, as the researchers, ought to know.

_____

_____

_____

_____

_____

_____

_____

_____

Thank you for completing this questionnaire.

General Health Questionnaire

Name……..

We want to know how your health has been in general over the last few weeks. Please read the questions below and each of the four possible answers. Circle the response that best applies to you. Thank you for answering all the questions.

Have you recently:

1. been able to concentrate on what you're doing?

better than usual (0) same as usual (1) less than usual (2) much less than usual (3)

2. lost much sleep over worry?

Not at all no more than usual rather more than usual much more than usual

3. felt that you are playing a useful part in things?

more so than usual same as usual less so than usual much less than usual

4. felt capable of making decisions about things?

more so than usual same as usual less than usual much less than usual

5. felt constantly under strain?

Not at all no more than usual rather more than usual much more than usual

6. felt you couldn't overcome your difficulties?

Not at all no more than usual rather more than usual much more than usual

7. been able to enjoy your normal day to day activities?

more so than usual same as usual less so than usual much less than usual

8. been able to face up to your problems?

more so than usual same as usual less than usual much less than usual

9. been feeling unhappy or depressed?

not at all no more than usual rather more than usual much more than usual

10. been losing confidence in yourself?

not at all no more than usual rather more than usual much more than usual

11. been thinking of yourself as a worthless person?

not at all no more than usual rather more than usual much more than usual

12. been feeling reasonably happy, all things considered?

more so than usual same as usual less so than usual much less than usual

General Health Questionnaire Scoring

Scoring - Likert Scale 0, 1, 2, 3 from left to right.
12 items, 0 to 3 each item Score
range 0 to 36.

Scores vary by study population. Scores about 11-12 typical.

Score >15 evidence of distress
Score >20 suggests severe problems and psychological distress

7-day recall Questionnaire

Name: **Date:** **Interviewer:**

1. Were you employed in the last seven days? 0. No (skip to Q4) 1. Yes
2. How many days of the last seven days did you work? _____ days
3. How many total hours did you work in the last seven days? _____ hours last week
4. What two days do you consider your weekend days? _____ _____
   (mark weekend days below with a squiggle)
5. Compared to your physical activity over the past three months, was last week's physical activity more, less or about the same? 1. More 2. Less 3. About the same

WORKSHEET

		DAYS						
	SLEEP	1 ___	2 ___	3 ___	4 ___	5 ___	6 ___	7 ___
MORNING	Moderate							
	Hard							
	Very hard							
AFTERNOON	Moderate							
	Hard							
	Very hard							
EVENING	Moderate							
	Hard							
	Very hard							
Total Min Per Day	Strength:	____	____	____	____	____	____	____
	Flexibility:							

Worksheet key:
An asterisk (*) denotes a work-related activity
A squiggly line through a column (day) denotes a weekend day

Rounding:
10-22 min. = 0.25; 2- 37 min. = 0.50;
38-52 min. = 0.75; 53-1.07 hr:min. = 1.0;
1.08-1.22 hr:min. = 1.25

Follow-up letter to participants at 3 months

Dear Sir/Madam

Thank-you for agreeing to be part of our study into activity levels among people suffering from acute low back pain. We appreciate your time and willingness to participate in this research trial.

In this study we want to ascertain how certain aspects of people's lives are affected by low back pain, in particular how their daily activity levels are influenced. We anticipate that the information gained from this study will help us to develop more effective ways of managing low back pain in the early and acute stages.

A key feature in the current management of low back pain is encouraging people to maintain certain levels of activity; often this is very specific to the individual. So far your participation in this study has enabled us to start seeing that activity levels vary considerably between people in the early stages of low back pain.

It is vital that we measure your activity levels again in XXX as this will enable us to build a comprehensive picture of how low back pain and activity are related to each other. Armed with this useful information we can then look forward to providing optimum ways for managing what is often a debilitating and frustrating problem for people.

Once again thank-you for your participation and I look forward to seeing you in a couple of weeks time. I will contact you to make an appointment. If you have any queries or questions please feel free to contact me using the details below.

Yours Sincerely

Paul Hendrick, BSc, Grad Dip Phys, MPhty
Physiotherapist
Tel: 03 479 5428
E mail paul.hendrick@otago.ac.nz

RT3 triaxial accelerometer in holster clip

Picture of set-up for calibration of RT3 units

RT3 monitor testing procedure on shaker table

RT3 accelerometer worn on right pelvis