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**The Measurement of Psychological Flexibility and
its Component Parts in Chronic Health Conditions**

– A Systematic Review,

and;

Psychological Flexibility in Prostate Cancer

Lindsay-Jo Sevier-Guy



**THE UNIVERSITY
of EDINBURGH**

Doctorate in Clinical Psychology

The University of Edinburgh

May 2018

Declaration of Own Work

Name: Lindsay-Jo Sevier-Guy

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Work: Chronic Health Conditions – A Systematic Review', and 'Psychological Flexibility
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Thank-you to my cohort for the support and fun and particular thanks to Katy and Ailsa for all that you do to make me smile. Finally, thank-you to my Fife family, **without you, I wouldn't be here.**

Dedication

I would like to dedicate this thesis to all the men who have lost their lives fighting prostate cancer or are living with its consequences. In particular, I would like to dedicate this thesis to my dearest friend Ben; you were my inspiration during this research and I know you would have loved to hear about the findings. Perhaps I can tell you all about it when I see you again.

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Chapter 1 – Thesis Portfolio Abstracts

Thesis Portfolio Abstract

Background

Whilst the role of Psychological Flexibility on psychosocial outcomes has been assessed in some chronic health conditions and cancers, its role in psychosocial outcomes in men with prostate cancer has not been established. Fear of cancer recurrence has been shown to be associated with poorer psychosocial outcomes. The relationship of Psychological Flexibility on the impact of fear of cancer recurrence has not been evaluated. Research into the measurement of Psychological Flexibility in individuals with chronic ill health has not revealed a definitive measure.

Methods

A systematic review of the reliability and validity of measures of Psychological Flexibility in individuals with chronic health conditions was conducted. A quality assessment of the included studies was conducted and relevant results were synthesised. A cross-sectional study utilising a survey methodology was conducted to establish the role of Psychological Flexibility and fear of cancer recurrence in psychological distress and quality of life in men with prostate cancer. Regression analyses were used to establish whether fear of cancer recurrence or Psychological Flexibility significantly predicted any variance in distress or quality of life. Whether Psychological Flexibility mediated or moderated the relationship between fear of cancer recurrence and psychosocial outcomes was assessed with conditional process analysis.

Results

The systematic review revealed no single definitive measure of Psychological Flexibility, and that many measures currently in use within research and clinical settings have not been fully validated in individuals with chronic ill health conditions. The cross-sectional study found that Psychological Flexibility and fear of cancer recurrence each significantly predict variance in psychological distress and quality of life. Psychological Flexibility mediated and moderated the relationship between fear of cancer recurrence and psychological distress and mediated the relationship between fear of cancer recurrence and quality of life.

Conclusions

In the absence of a definitive measure of Psychological Flexibility, information on the measures identified were provided to allow clinicians and researchers to choose the most appropriate measure for their use. Future research might focus on further validation of existing measures of Psychological Flexibility rather than the development of additional measures. The challenges underlying using a psychometric approach to measure contextual science concepts was discussed. Due to the role of Psychological Flexibility within psychosocial outcomes in prostate cancer, it was suggested as a potential treatment target. The relevance of treatments such as Acceptance and Commitment Therapy, which aim to increase Psychological Flexibility, for men with prostate cancer was discussed. Future research avenues to further assess the role of Psychological Flexibility in psychosocial outcomes was discussed.

Thesis Portfolio Lay Summary

Psychological Flexibility includes things like how well a person copes and adapts to different psychological demands, shifts their perspective depending on their situation, and balances competing demands on them. Individuals who report higher Psychological Flexibility also report higher quality of life, lower psychological distress and greater overall wellbeing. Psychological Flexibility is often measured with questionnaires. We do not know which of these questionnaires is the most appropriate one to use. The scientific literature was investigated to assess what tools for measuring Psychological Flexibility already exist, and how well validated (how well assessed) they are. This identified that there is not one tool that can be recommended to measure Psychological Flexibility. Future research could look at assessing the existing tools more fully rather than trying to develop new measures.

Having a diagnosis of prostate cancer can be linked with lower quality of life and higher psychological distress. Men with prostate cancer can also fear that the cancer will come back now or in the future. In other types of health conditions, higher levels of Psychological Flexibility have been shown to be linked with higher levels of quality of life and lower levels of psychological distress. The role of Psychological Flexibility on these outcomes in men with prostate cancer has not been established. This study showed that Psychological Flexibility and fear of cancer recurrence explain some of the differences found in quality of life and psychological distress in different men with prostate cancer. Psychological Flexibility also explains some of the relationship between fear of cancer recurrence and outcomes such as distress and quality of life. Psychological Flexibility may also act as a protective factor against the negative impact of fear of cancer recurrence.

Chapter 2 – Systematic Review

The Measurement of Psychological Flexibility and its Component Parts in Chronic Health Conditions – A Systematic Review

Written according to guidelines for Assessment (see Appendix 2.A)

Title for Running Head: Measurement of Psychological Flexibility in Chronic Health
Conditions

Lindsay-Jo Sevier-Guy

School of Health and Social Science, University of Edinburgh¹; Psychology
Department, NHS Fife²

David Gillanders

School of Health and Social Science, University of Edinburgh¹

Nuno Ferreira

School of Health and Social Science, University of Edinburgh¹

Kate Kennedy

Psychology Department, NHS Fife²

Authors Note

¹School of Health and Social Science, Clinical Psychology, Doorway 6, Teviot Place,
Edinburgh, EH8 9AG; ²Psychology Department, Stratheden Hospital, Cupar, KY15
5RR.

Dr Nuno Ferreira is now at School of Humanities and Social Sciences, University of Nicosia.

This review was conducted as part of the lead **author's Doctoral Degree, the fees of** which are paid for by NHS Education for Scotland (NES).

Correspondence regarding the article should be addressed to Lindsay-Jo Sevier-Guy, Psychology Department, Stratheden Hospital, Cupar, KY15 5RR. E-mail: s1580020@sms.ed.ac.uk.

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Abstract

Psychological Flexibility/Inflexibility has been shown to be related to quality of life, psychological distress and other important outcomes in individuals with chronic health conditions. There is currently no consensus on the measures of Psychological Flexibility/Inflexibility that should be used. Studies that assessed the reliability and validity of psychometric measures of Psychological Flexibility/Inflexibility in chronic ill health populations were reviewed. No definitive measure of Psychological Flexibility /Inflexibility was identified, and few measures had their reliability and validity completely established. Criteria to aid clinicians and researchers in choosing a measure are presented. Key challenges regarding the application of psychometric theory to contextual science concepts are discussed.

Keywords

Psychological Flexibility

Psychological Inflexibility

Measurement

Chronic Health Conditions

Contextual Science

Psychometric

Psychological Flexibility is an important part of psychological health and is defined by Kashdan (2010) as how well a person copes and adapts to varying psychological demands, applies mental resources flexibly, shifts their perspective depending on their context, and how well they balance competing demands on them. It is also proposed that the elements of Psychological Flexibility have opposing counterparts which, taken together, are described as Psychological Inflexibility. Kashdan (2010) describes this as encompassing the other extreme of those elements of Psychological Flexibility and is characterised by an individual who is rigid, lacks sensitivity to context, and is inflexible in their thinking.

Psychological Flexibility/Inflexibility underlies **the therapeutic modality "Acceptance and Commitment Therapy"** (Hayes *et al.*, 1999) which proposes that this model of human behaviour consists of twelve core processes that are all interlinked. It is proposed that individually, six of these processes are related and together form the **overall construct of "Psychological Flexibility"** (often conceptualised as a hexaflex, see Figure 2.1). These six processes are said to be one side of the coin, each having their own counterpart, which together form **"Psychological Inflexibility"** (Figure 2.1) (Hayes *et al.*, 2006). ACT theorises that individuals who are more psychologically flexible are better able to make values-consistent behavioural choices in their own lives.

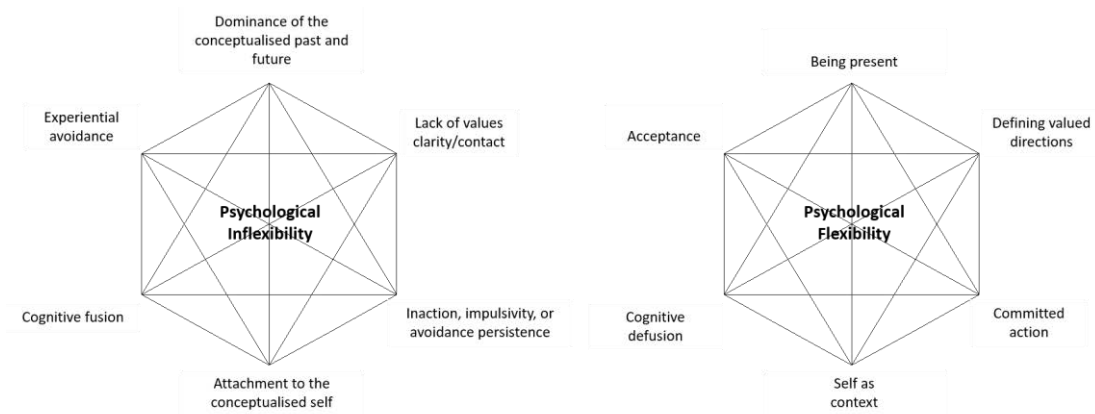


Figure 2.1 – The Acceptance and Commitment Therapy (ACT) model of psychopathology (also known as the ACT hexaflex), two sides of the coin, adapted from Luoma *et al.* (2007).

Psychological Flexibility as a model of human behaviour has developed from other behavioural theories that underlie psychological ill health. In a paper by Hayes *et al.* (1996) experiential avoidance was discussed, describing it as a process of not being willing to stay in contact with unpleasant private experiences, and attempts by an individual to change these experiences or avoid the contexts that prompt these experiences. This concept is an extension of the idea of avoidance of private experiences which is found in many psychological theories such as repression in **Freudian theories or avoidance in Foa's behavioural theories (Hayes *et al.*, 1996)**. This theory of experiential avoidance was built on and became part of the Psychological Flexibility model (Hayes *et al.*, 2006). More recently, several authors have suggested changes to the way the model of Psychological Flexibility is conceptualised in addition to the six processes and the unified element of Psychological Flexibility. Some authors suggest that Psychological Flexibility can be **thought of as two broader processes. Firstly "acceptance and mindfulness**

processes” and secondly “commitment and behaviour change processes” (Hayes *et al.*, 2010) (see Figure 2.2). Other authors have suggested that the model can be thought of as involving three broad response styles, which are labelled open, aware and engaged (Hayes *et al.*, 2010) (Figure 2.3).

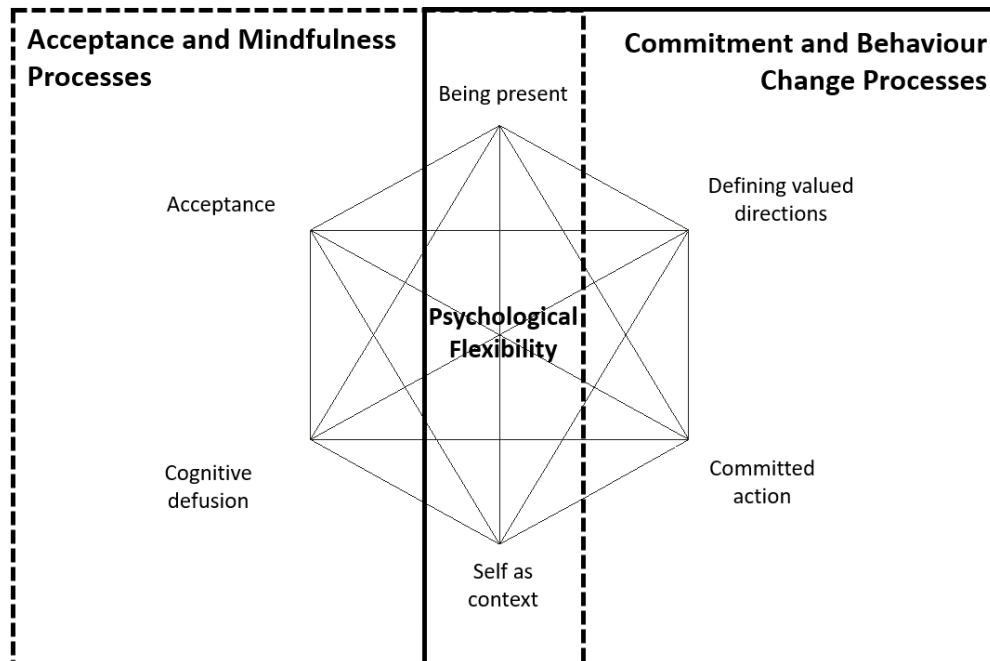


Figure 2.2 – Diagram of Psychological Flexibility highlighting two potential overarching processes; ‘acceptance and mindfulness processes’ (dashed line box) and ‘commitment and behaviour change processes’ (solid line box). Note being present and self as context are conceptualised as falling under both types of processes. Adapted from Luoma *et al.* (2007).

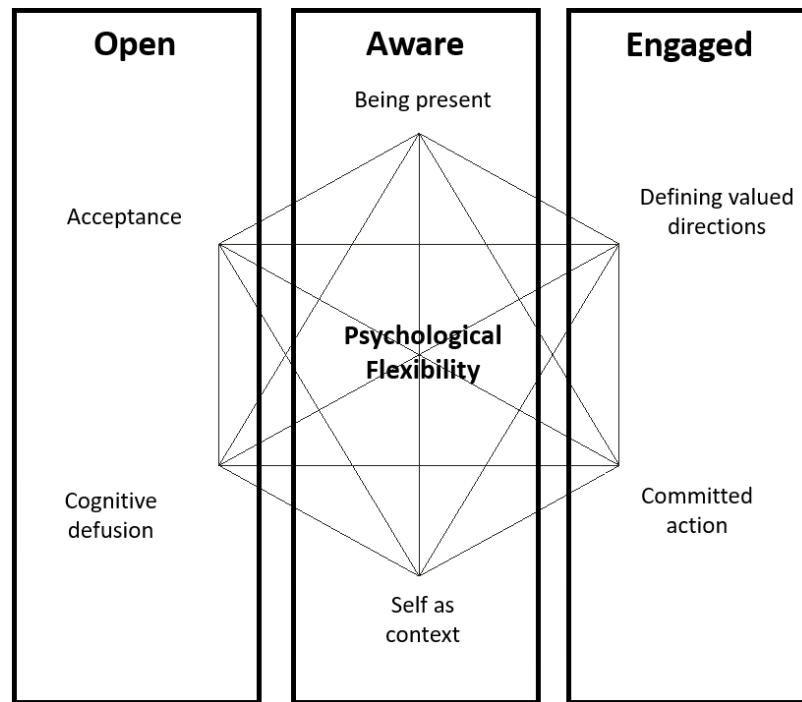


Figure 2.3 – Model of Psychological Flexibility with overlays demonstrating three potential response styles.

Regardless of how Psychological Flexibility is conceptualised, research shows associations with increased QoL, lower psychological distress and greater wellbeing (Kashdan & Rottenberg, 2010). This finding has been replicated in clinical health populations (McCracken & Velleman, 2010) and authors have found that Psychological Flexibility explains variance in impairment over and above that which is already explained by other established variables such as anxiety, depression, stress or neuroticism (Gloster *et al.*, 2011), highlighting the importance of this process in explaining individual differences in mental health.

Our knowledge of human suffering is always expanding and this creates a need for new, valid and reliable measures of psychological constructs (Boyle *et al.*, 2015). Systematic reviews of measures often show a diversity across literature of the

reliability and validity of these measures, whether it is due to the population under investigation, differences in application or individuals' differences (e.g. Bjelland *et al.*, 2002). Whilst Boyle *et al.* (2015) suggest that better measures are needed, they also highlight the associated difficulty with the increasing number of measures causing difficulty for researchers and clinicians to be able to effectively discern what measures are most appropriate. Boyle *et al.* (2015) also suggest that when evaluating measures of psychological constructs not only should reliability and validity of these measures be assessed, but also practical elements such as cost, ease of use and length of scale.

Within a functional contextual framework, describing the model in different ways (e.g. as one process, as three processes, as six processes) is not problematic, as within this perspective, the words or concepts are adapted to the needs of the context, rather than being used to represent a specific concrete concept. However, this does have implications for the development of measures of this construct, particularly as the development of measures is often based within an elemental realism framework (e.g. Pepper, 1942). Within this framework, concepts to be measured are assumed to be concrete and exist in an objective reality, separate from the observer. It is then the role of the researcher to be able to attempt to best quantify this concept, often with the use of psychometric measures, which are often assessed in terms of how well that measure is assessing that specific, concrete concept. However, the functional contextual view would be that concepts to be assessed are not concrete and external to us, but that the way we view concepts and how we measure them will in itself change that concept under investigation. This results in a challenge for researchers assessing Psychological Flexibility or

interventions that aim to change this concept. To assess change and make an argument for the usefulness of these concepts, we need to be able to measure them in some way. Traditional methods of measurement tend to be psychometric assessment, and therefore, psychometric measures are developed to assess Psychological Flexibility in a concrete way. As described, this can result in difficulties in regards to this fluid concept. Farhall *et al.* (2013) recognised that developing valid measures of third wave constructs is a challenge due to the differences in the literature regarding whether elements of the ACT hexaflex should be evaluated individually or whether overarching concepts such as Psychological Flexibility/Inflexibility should be assessed. There are different opinions in the literature regarding the measure of Psychological Flexibility/Inflexibility with Rolffs *et al.* (2016) suggesting that as Psychological Flexibility/Inflexibility in theory covers twelve processes and that all of these should be considered when evaluating this construct. However, other authors have recognised the fluid nature of this construct and that the model is still developing (Francis *et al.*, 2016).

There are many diverse measures of third wave constructs. These include global measures of Psychological Flexibility/Inflexibility, measures of elements of the hexaflex and measures that are designed for specific populations. The Acceptance and Action Questionnaire (AAQ-II; Bond *et al.*, 2011) is the most often used measure of Psychological Inflexibility. Some authors have argued that the AAQ-II does not measure all facets of Psychological Flexibility, instead only measuring some of the twelve processes that make up the ACT model (Figure 2.1) (Wolgast, 2014). Indeed, even in the original validation paper by Bond *et al.* (2011) the AAQ-II is described variably as measuring acceptance, experiential avoidance and

Psychological Inflexibility. Studies looking at the factor structure of the AAQ-II appear to reveal that this measures a unified process supporting it as a measure of Psychological Flexibility rather than of acceptance/experiential avoidance (Wolgast, 2014). However, recent research has suggested that perhaps this unified concept is not Psychological Flexibility but that the AAQ-II is actually measuring a broader concept like neuroticism (Rochefort *et al.*, 2017). It is sometimes difficult to discern how global measures of Psychological Flexibility such as the AAQ-II link to, and are explicitly measuring, each of the elements of the hexaflex (Rolffs *et al.*, 2016). Other authors suggest that by attempting to measure each element of the hexaflex in isolation a sense of the global concept of Psychological Flexibility can be lost (Francis *et al.*, 2016).

Farhall *et al.* (2013) propose that measures of these third wave constructs might need to be population specific. Wolgast (2014) suggest that further measures of Psychological Flexibility need to be identified that are contextually appropriate – for example, those that are validated in a specific population. The use of ACT within ill health populations is well-established with the American Psychological Association recognising it as an evidenced-based treatment for chronic pain (Hayes *et al.*, 2012). This has led to some measures that are not necessarily validated in an ill health population being used to investigate change in interventions for this population. It has also led to other measures being developed specifically for these populations.

Aim

Psychological Flexibility is being increasingly researched as part of the growing evidence base for ACT, particularly in chronic ill health populations. This research often relies on the AAQ-II (Bond *et al.*, 2011), despite this measure not being validated specifically in a clinical health population. Recently, authors have also questioned the validity of the AAQ-II, suggesting that it is perhaps measuring a broader concept than Psychological Flexibility (Rochefort *et al.*, 2017). Newer measures of Psychological Flexibility are being developed (e.g. Rolffs *et al.*, 2016; Francis *et al.*, 2016), which adds to the number of available measures without resolving which measures are valid for use in which populations. Therefore, this review will attempt to clarify what measures of Psychological Flexibility are available and valid. As some authors suggest that measures need to be evaluated in line with their use in a specific population (e.g. Farhall *et al.*, 2013) this review will focus on papers that are investigating the reliability and validity of measures for use in a chronic ill health population.

The key questions that this review hopes to address are:

1. What measures of psychological flexibility have been validated in a chronic ill health population?
2. What are the psychometric properties of these tools?

Methods

Protocol

The review was conducted using an a priori defined protocol that was published on the Prospero website (Protocol Number: CRD42017056033; www.crd.york.ac.uk/PROSPERO/display_record.php?RecordID=56033). The protocol

was adapted to widen the remit of the review and this change is also recorded on the website. This change was undertaken as during the initial search it became clear that to limit to measures that assessed Psychological Flexibility in its entirety would not be possible because some assessment measures were claimed to measure all of Psychological Flexibility in one paper, but only sections in another. This lack of clarity in the definition of Psychological Flexibility used by some authors led to the change in protocol.

Search Strategy

The following databases were searched; PsychINFO, Medline, Psychological and Behavioural Science Collection, CINAHL Plus and the Cochrane Central Register of Controlled Trials (CENTRAL). In order to include any relevant papers that were not identified in the initial search strategy, further to interrogating these databases, additional searches were conducted. The reference lists of relevant systematic reviews that were identified in this search were examined to identify further possible papers. Measures of Psychological Flexibility that were identified from this search were investigated to identify the original paper, and then citations from this paper were searched for any additional relevant papers. Any researchers that were first authors on more than one relevant paper identified through the original search strategy were emailed to request any relevant unpublished data that they may have that could be included in the review. The first authors for the original papers of relevant measures were also emailed to request any unpublished work related to the reliability and validity of those measures specifically. Finally, a Google Scholar search was performed and the first ten pages (i.e. the top 100 results) were

interrogated for further articles not already identified. The search criteria and keywords used for each database can be found in supplementary file S2.1.

Inclusions/Exclusion Criteria

1. Types of study – only primary research papers were included. Books, book chapters, book reviews and reviews were all excluded.
2. Assessing the reliability and validity of a tool that aims to measure an element of Psychological Flexibility as defined originally by Hayes *et al.* (2006) and described in Luoma *et al.* (2007) – Papers that assessed the reliability or validity of a measure that aimed to assess any aspect of the Psychological Flexibility hexaflex as described in Luoma *et al.* (2007) were included. Papers that did not assess the reliability or validity of an aspect of Psychological Flexibility as found in Luoma *et al.* (2007) but only used the measure to assess change in an intervention were excluded.
3. Population – to be included a paper needed to have used participants who have some form of chronic health condition (e.g. chronic pain, epilepsy, cancer). If a paper included several populations (e.g. a student population and a chronic pain population), then this paper was included if it was possible to assess the health population separately. Papers were excluded if they did not contain a chronic ill health population.

Data extraction

Following the identification of potential literature using the search strategy, these papers were interrogated using the above inclusion and exclusion criteria. Papers were screened initially by title, then by abstract and finally following a complete

read through of the remaining papers. One author (LJSG) completed this process, with any queries being discussed with a second author (NF).

Risk of bias assessment

A quality assessment tool specific to the aims of this review was developed (supplementary file S2.2). One author (LJSG) reviewed all papers using this tool. Another author (KK) reviewed a third of the papers in order to assess the reliability of the tool. A kappa agreement score was developed to assess the similarity of the **two rater's scores. Following this, any disagreements were discussed and resolved** for the dual rated papers to arrive at the final ratings for each paper. Any disagreements that could not be resolved between the two raters were discussed with another author (DG).

Assessing the quality of the measures

In order to assess whether the measures themselves are of sufficient quality, the following criteria were used (adapted from van Saane and colleagues (2003). Internal consistency should be 0.80 or higher and test-retest reliability should be 0.70 or higher. Regarding construct validity; for convergent validity (assessing the current measure against another measure that purports to measure the same construct) the correlation between these should be 0.50 or higher and for discriminant validity (the current measure is associated with another measure that assesses a similar but distinct concept), the correlation between them should be 0.50 or lower. For content validity, whether or not the questions used in the measure relate to the construct under measurement needs to have been established. This could be completed in several ways, for example, having the

measure assessed by an expert in the field as clearly assessing the construct, or using a translation process that involves ascertaining that translated questions remain related to the original concept. Finally, criterion validity was assessed as sufficient if the measure was assessed against other constructs that are hypothesised to be related to the construct under investigation, and correlations with these constructs were at the magnitude and direction previous literature would suggest. The overall quality criteria are included in box 2.1.

| | | |
|--------------------------------|---|-------|
| Internal Consistency | | >0.80 |
| Test-Retest Reliability | | >0.70 |
| Construct Validity | Convergent | >0.50 |
| | Discriminant | <0.50 |
| Content | Measure's questions clearly relate to overall construct | |
| Criterion | Measure correlates with related concepts as hypothesised by previous literature | |

Box 2.1 – Quality criteria for the measures under investigation, adapted from van Saane et al. (2003).

Data synthesis strategy

Due to the likely heterogeneity of the studies in terms of the diverse populations likely to be identified and the many different measures, a meta-analytical synthesis was not proposed. Therefore, a narrative synthesis of the data from each paper will be completed. The main data to be extracted will be the tools in use in a clinical health population, the reliability and validity of these tools, the aspects of Psychological Flexibility that are assessed by these tools and elements about the usability of these tools. 'Usability' covered elements such as whether these tools were free to use, their length, whether they were easy to score or interpret and whether they were acceptable to patients.

Results

Study selection

Figure 2.4 shows the study selection process for this review. In brief, 471 records were identified and 30 were remaining at the end of the study selection process for inclusion in the review. Figure 2.4 also denotes the reasons for papers being excluded.

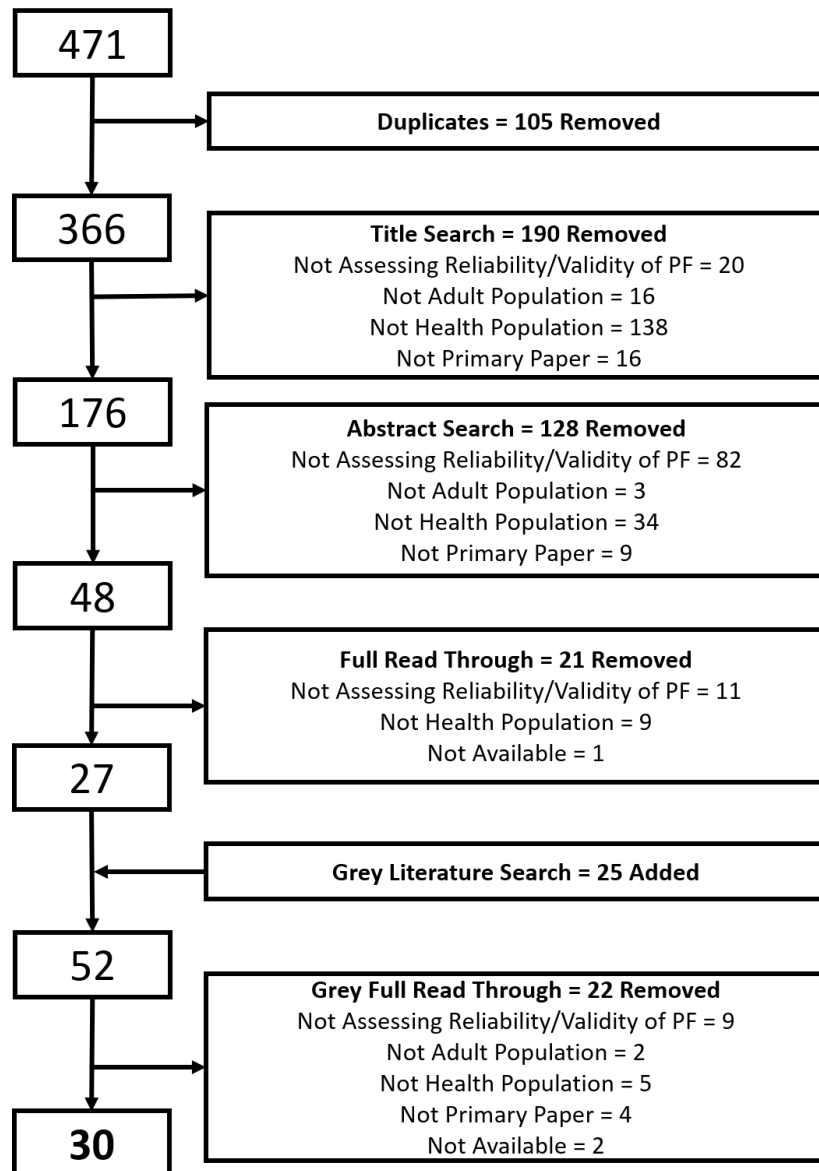


Figure 2.4 – Demonstrates the selection of studies for this review. Abbreviations: PF (Psychological Flexibility)

Quality Assessment

Quality ratings for each of the studies is included in Table 2.2. Inter-rater reliability of the one third of the sample that was originally co-rated revealed a Kappa of 0.49 which is under 0.70, the level considered satisfactory (Pallant, 2010). It became clear that the majority of disagreement was between poor and adequate or adequate and well, with very few instances where there was disagreement between poor and well. This suggests that it was the finer grading included in the quality criteria that made inter-rater reliability less accurate. The finer grading issue was discussed between the raters to gain greater clarity. Following this, it was agreed that the co-rater would rate the remaining two thirds of papers. This was with the aim of ensuring that the final quality ratings for each paper were the combination of **both raters' decisions regarding the quality of each paper in an attempt to reduce bias**. The inter-rater agreement improved following this process and the final Kappa level for all papers combined was 0.68. Although this was still below the commonly described level of 0.70, it did represent an improvement from the original inter-rater agreement. **Please note this Kappa score does not include the score for the 'overall validity' or 'overall reliability' ratings. This is because these ratings are based purely on previous ratings and would have therefore skewed the Kappa score.**

Overall the rating for the studies revealed they were of fairly poor quality. Internal consistency was often reported accurately and rated as 'well **covered**', whereas test re-test reliability was often not assessed. This led to several papers being rated poorly for overall reliability, as they tended to claim that reliability of the scale had been established in the conclusions, despite only part of reliability being assessed. Regarding validity, there was a mix across the papers; several were rated as poorly

assessing validity, whereas others did manage to assess validity in an adequate or well covered way. Sample size was rarely assessed a priori and often the adequacy of the sample size for the analysis being used was not discussed at all. This has resulted in sample size being rated as poorly addressed across the majority of the studies. Sample representativeness was also often rated as poor. Despite samples often being well described, the samples used were limited to a more specific population (for example, individuals with chronic pain attending a specialist pain service in one geographical area) and therefore this limits the generalisability of the overall results. The usability of the scale under investigation (for example is it short, easy to use/administer or easy to score) was rarely discussed in the included studies and therefore, was again, rated as poorly addressed in most studies. The discussions of most papers were rated highly as indicated by positive rating of the conclusions being in line with the data, the implications of the study on the wider literature and for future research, and the limitations of the studies being clearly set out.

Study characteristics

Characteristics for each study can be seen in Table 2.1. Despite including studies that had any health population, the majority of studies (80.0%) included a chronic pain population. Some studies used a specific chronic pain population, for example fibromyalgia (e.g. Yu *et al.*, 2017) or whiplash associated disorder (Wicksell *et al.*, 2009), but most included a heterogeneous chronic pain population defined as **individual's experiencing pain for three months or more. Other samples found in the review were;** people with tinnitus (Weise *et al.*, 2013), cardiovascular disease (Spatola *et al.*, 2014), irritable bowel syndrome (IBS) (Ferreira *et al.*, 2013), Multiple

Sclerosis (MS) (Gillanders, *et al.*, 2014) and epilepsy (Lundgren *et al.*, 2012). The studies included have a high proportion of women participants. Over all the studies there was an average of 70.15% female participants. Most studies assessed elements of both reliability and validity, two assessed only reliability (Bailey, 2016; Weise *et al.*, 2013), and three assessed only validity (Lundgren *et al.*, 2012; Pielech *et al.*, 2016; Wicksell *et al.*, 2008). Studies assessed questionnaires in a variety of languages and those that were both population specific and generic measures. Measures were identified that attempted to measure Psychological Flexibility/Inflexibility as a whole (e.g. Han *et al.*, 2017) and those that attempted to measure individual parts of the hexaflex such as values (e.g. Åkerblom *et al.*, 2017).

Reliability and Validity of Measures

Tables 2.3 and 2.4 combine the results across the studies found in this review on the different measures for those measuring Psychological Flexibility (Table 2.3) and those that are measuring separate elements of the hexaflex (Table 2.4). The quality criteria used to assess the measures can be found in box 2.1.

Measures of Psychological Flexibility/Inflexibility

Psychological Inflexibility in Pain Scale (PIPS): The PIPS was the most well researched measure of Psychological Flexibility across this review. Reliability and validity of this measure has been established across all the studies using the PIPS. However, the studies using the PIPS are, in reality, using measures that are either of different lengths, for example, 16 items (Wicksell *et al.*, 2008) instead of 12 items (Wicksell *et al.*, 2010) or using different language versions (e.g. Trompetter *et al.*, 2014). Each individual iteration of the PIPS has not had their psychometric

properties fully established, with the exception of the Spanish version of the PIPS (Rodero *et al.*, 2013).

Brief Pain Response Inventory (BPRI): English and Korean versions of this were assessed in this review. The Korean version of this scale has established psychometric properties with the exception of construct and criterion validity which has not been established (Han *et al.*, 2017). For the English version of this scale, only construct validity and internal consistency has been established (McCracken *et al.*, 2010).

Brief Pain Coping Inventory – 2 (BPCI-2): This is the longest measure of Psychological Flexibility/Inflexibility included in the review (19 items). The validity of this measure has been assessed (McCracken & Vowles, 2007), however, the reliability (both internal consistency and test re-test reliability) have not been established. Of the English Psychological Flexibility/Inflexibility measures identified through this review, the BPCI-2 is the most psychometrically robust.

Cardiovascular Disease Acceptance and Action Questionnaire (CVD-AAQ): This Italian questionnaire is specific to a Cardiovascular Disease (CVD) patient population. Both reliability and validity have been established for this measure with the exception of internal consistency which did not meet the required level of 0.80. (Spatola *et al.*, 2014). It is also one of the shortest measures found, containing seven items.

Overall, the complete psychometric properties of measures of Psychological Inflexibility/Flexibility has not been established or investigated for any measure included in this review with the exception of the Spanish version of the PIPS (Rodero *et al.*, 2013). However, this measure is limited in the fact that it is only

suitable for native Spanish speakers and it was conducted on individuals with fibromyalgia. Information regarding measures of Psychological **Flexibility/Inflexibility's** usability is also missing from the included studies. The length of the measures of Psychological Flexibility/Inflexibility is reasonably short, ranging from 7-19 items. All measures identified in this study are population specific (all chronic pain except the CVD-AAQ which is for CVD populations).

Measures of elements of the hexaflex

Acceptance: All measures of acceptance found in this review were designed to be population specific, including the Chronic Pain Acceptance Questionnaire (CPAQ) and its shorter form (CPAQ-8), the Acceptance of Irritable Bowel Syndrome (IBSAAQ), the Multiple Sclerosis Acceptance Questionnaire (MSAQ) and the Tinnitus Acceptance Questionnaire (TAQ). The CPAQ has both English and Swedish versions. The English version has only had its internal consistency and criterion validity assessed (e.g. Fish *et al.*, 2010), whilst the Swedish version had these and Content Validity assessed (Wicksell *et al.*, 2009). The shorter version of eight items (CPAQ-8) was only found in English in this review and demonstrated reasonable psychometric properties (Fish *et al.*, 2010; Fish *et al.*, 2013) with only content and construct validity not being established. The IBSAAQ was assessed in one study (Ferreira *et al.*, 2013) and this demonstrated psychometric properties of the measure across all elements of reliability and validity assessed in this review. The MSAQ also demonstrated reasonable psychometric properties with all but test-retest reliability being established (Pakenham *et al.*, 2011). The German TAQ has not had its psychometric properties established, with only data on internal consistency being found in this review (Weise *et al.*, 2013).

Cognitive Fusion: The cognitive fusion questionnaire (CFQ) was the only measure identified in the included papers that assessed cognitive fusion specifically. This measure has seven items (although an older version assessed in one paper contained 13 items; McCracken *et al.*, 2014). Despite the paper included in this review (Gillanders *et al.*, 2014) discussing the validation of the CFQ across other samples more fully, within the context of physical health conditions the English version of the seven item CFQ has had its reliability and validity established in participants with MS with the exception of test-retest reliability and construct validity. Scale usability was also discussed for the English version of the CFQ with its suitability for clinical practice due to its length, its simple language increasing acceptability and the generic nature of the scale making it suitable across clinical and research settings being highlighted. A French version of the seven item CFQ was also found in this review and its psychometric properties were established within a French speaking Canadian sample, with the exception of test-retest reliability (Dionne *et al.*, 2016).

Committed Action: This review identified several iterations of the Committed Action Questionnaire (CAQ) including the original 18 item CAQ, the shorter eight item version (CAQ-8) and the Chinese translation of the short version (ChCAQ-8) all of which are not population specific. Swedish and English versions of the CAQ and the CAQ-8 and a French version of the CAQ-8 were found. The Swedish versions demonstrated similar psychometric properties to each other with all but test-retest reliability being established (Åkerblom *et al.*, 2016). The English CAQ version demonstrated good psychometric properties with again, all but test-retest reliability and criterion validity being established (Bailey, 2016). Regarding the shorter English language version of the CAQ-8, neither test-retest reliability nor content validity

were established in this review (McCracken, 2013). The French CAQ-8 demonstrated good psychometric properties with all but test-retest being established in this review (Gagnon *et al.*, 2017). Finally, a Chinese version of the CAQ (the ChCAQ-8) failed to demonstrate internal consistency, construct validity or test-retest reliability in this review (Wong *et al.*, 2016).

Experiential Avoidance: Only one measure for experiential avoidance was identified in this review, the Acceptance and Action Questionnaire-II, Pain Version (AAQ-II-P) which is population specific to individuals with chronic pain. Only construct validity and internal consistency has been demonstrated in this seven-item questionnaire in this review (Reneman *et al.*, 2014).

Self as Context: Again, only one measure for self as context was identified; the Self Experiences Questionnaire (SEQ). This eleven-item questionnaire is not population specific, however was only assessed with a chronic pain and fibromyalgia population in this review. Across these two studies, all but test-retest reliability was established (Yu *et al.*, 2016; Yu *et al.*, 2017).

Values: Both population specific and generic measures of values were identified. Of **the generic measures, the Bull's Eye Value Survey** has not adequately demonstrated reliability or validity in this review (Lundgren *et al.*, 2012). The second generic measure, the Values Tracker (VT), demonstrated only criterion validity, but a paper did discuss how its length (two items) made it easy to use and administer (Pielech *et al.*, 2016). The Chronic Pain Values Inventory (CPVI), is a measure of values specifically designed for a chronic pain population. The CPVI is in Swedish and validity was established in this review (Åkerblom *et al.*, 2017), but reliability was not (neither internal consistency or test retest).

Risk of bias across studies

Some studies were conducted by the same author group and appeared to be recruiting from the same population (e.g. McCracken *et al.*, 2010 and McCracken *et al.*, 2014). Although it is not clear that the same participants are being used, the population from which the participants are being recruited from do appear to be the same. This would limit the generalisability of the overall synthesis of the results as, despite there being several papers assessing the reliability and validity of a measure, the population (e.g. a specialised chronic pain service in one geographical area) the samples are being recruited from is the same and therefore it is less clear how valid or reliable the measure may be in a different population; for example, one that is taken from a different area of the country or a different pain service with differing socio-economic or pain diagnoses distribution.

Table 2.1

| Primary Author (Date) | Health Pop | % Female | Assessing Reliability or Validity? | α (full scale) | Measure | All or part of PF? | Length | Free | Pop Specific? | Ease of Use Discussed | Language Validated in? |
|------------------------------|-------------------|-----------------|---|---|----------------|---------------------------|----------------------------|-------------|----------------------|------------------------------|-------------------------------|
| Åkerblom (2016) | Chronic Pain | 72.1 | Both | 0.89 (CAQ-18) 0.84 (CAQ-8) | CAQ CAQ-8 | Part (Committed Action) | 18 (CAQ) 8 (CAQ-8) | n.r. | No | yes | Swedish |
| Åkerblom (2017) | Chronic Pain | 85.3 | Both | n.r. | CPVI | Part (Values) | 12 | n.r. | Yes (Pain) | yes | Swedish |
| Bailey (2016) | Chronic Pain | 62.0 | Reliability | 0.90 (18 item) 0.91 (17 items) | CAQ | Part (Committed Action) | 18 (17 used for α) | n.r. | No | no | English |
| Barke (2015) | Chronic Pain | 70.3 | Both | 0.78 | PIPS | All** | 12 | n.r. | Yes (Pain) | no | German |
| Dionne (2016) | Chronic Pain | 79.6 | Both | 0.94 | CFQ | Part (Cognitive Fusion) | 7 | n.r. | No | yes | French |
| Ferreira (2013) | IBS | 88.4 | Both | 0.89 | IBSAAQ | Part (Acceptance) | 19 | n.r. | Yes (IBS) | no | English |
| Fish (2010) | Chronic Pain | 81.4 | Both | 0.86-0.89 (CPAQ) 0.78-0.85 (CPAQ-8) | CPAQ CPAQ-8 | Part (Acceptance) | 20 (CPAQ) 8 (CPAQ-8) | n.r. | Yes (Pain) | no | English |

| | | | | | | | | | | | |
|-------------------|--------------|-----------|----------|-----------|--------------------------|-------------------------------|----|------|------------|-----|-------------------------|
| Fish (2013) | Chronic Pain | 73.0-85.0 | Both | 0.79-0.82 | CPAQ-8 | Part (Acceptance) | 8 | n.r. | Yes (Pain) | no | English |
| Gagnon (2017) | Chronic Pain | 78.4 | Both | 0.86 | CAQ-8 | Part (Committed Action) | 8 | n.r. | No | no | French |
| Gillanders (2014) | MS | 72.0 | Both | 0.93 | CFQ | Part (Cognitive Fusion) | 7 | n.r. | No | yes | English |
| Han (2017) | Chronic Pain | 51.9 | Both | 0.82 | K-BPRI | All | 15 | n.r. | Yes (Pain) | no | Korean |
| Lundgren (2012) | Epilepsy | 51.8 | Validity | n/a | Bull's-Eye Values Survey | Part (Values) | 3 | n.r. | No | no | South African (Various) |
| McCracken (2007) | Chronic Pain | 64.4 | Both | 0.73 | BPCI-2 | All | 19 | n.r. | Yes (Pain) | no | English |
| McCracken (2010) | Chronic Pain | 65.7 | Both | 0.84 | BPRI | All | 15 | n.r. | Yes (Pain) | no | English |
| McCracken (2013) | Chronic Pain | 62.5 | Both | 0.91 | CAQ | Part (Committed Action) | 18 | n.r. | No | no | English |
| McCracken (2014) | Chronic Pain | 67.8 | Both | 0.87 | CFQ | Part (Cognitive Fusion) | 13 | n.r. | No | no | English |
| McCracken (2015) | Chronic Pain | 62.0 | Both | 0.87 | CAQ-8 | Part (Committed Action) | 8 | n.r. | No | no | English |
| Pakenham (2011) | MS | 85.0 | Both | 0.83 | MSAQ | Part (Acceptance) | 16 | n.r. | Yes (MS) | no | English |
| Pielech (2016) | Chronic Pain | 64.8 | Validity | n/a | VT | Part (Values) | 2 | n.r. | No | yes | English |
| Reneman (2014) | Chronic Pain | 73.0 | Both | 0.87 | AAQ-II-P | Part (Experiential Avoidance) | 7 | n.r. | Yes (Pain) | no | Dutch |

| | | | | | | | | | | | |
|-------------------|--------------|------|-------------|--|---------|-------------------------|----------------------------|------|--------------------|-----|---------------------|
| Rodero (2013) | Fibromyalgia | 95.0 | Both | 0.90 | PIPS | All** | 12 | n.r. | Yes (Pain) | no | Spanish |
| Spatola (2014) | CVD | 21.8 | Both | 0.79 | CVD-AAQ | All | 7 | n.r. | Yes (CVD Patients) | no | Italian |
| Trompetter (2014) | Chronic Pain | 72.0 | Both | 0.88 | PIPS | All** | 12 | n.r. | Yes (Pain) | no | Dutch |
| Weise (2013) | Tinnitus | 39.4 | Reliability | 0.86 | TAQ | Part (Acceptance) | 12 | n.r. | Yes (Tinnitus) | no | German |
| Wicksell (2008) | Chronic Pain | 80.8 | Validity | 0.89 | PIPS | All** | 16 | n.r. | Yes (Pain) | no | Swedish |
| Wicksell (2009) | WAD | 74.8 | Both | 0.91 | CPAQ | Part (Acceptance) | 20 (19 used for a) | n.r. | Yes (Pain) | no | Swedish |
| Wicksell (2010) | Chronic Pain | 74.8 | Both | n.r. | PIPS | All** | 12 | n.r. | Yes (Pain) | no | Swedish |
| Wong (2016) | Chronic Pain | 70.0 | Both | 0.75 | ChCAQ-8 | Part (Committed Action) | 8 | n.r. | No | yes | Chinese (Cantonese) |
| Yu (2016) | Chronic Pain | 65.2 | Both | 0.90 | SEQ | Part (Self as Context) | 15 | n.r. | No | no | English |
| Yu (2017) | Fibromyalgia | 93.3 | Both | 0.94* whole scale or cut down - not clear | SEQ | Part (Self as Context) | 15 (11 used for a) | n.r. | No | no | English |

Table 2.1 – Relevant characteristics of each of the included studies.

* It is not clear whether this **a level** is for the whole scale of 15 items or for the cut down scale of 11 items

** Authors claim to measure all of Psychological Flexibility, but in reality, only measures two parts of the hexaflex (Avoidance and Cognitive Fusion).

Abbreviations: Pop (Population); PF (Psychological Flexibility); n.r. (not reported); **α (Chronbach's alpha level); n/a (not applicable); IBS (Irritable Bowel Syndrome); CVD (Cardiovascular Disease); WAD (Whiplash Associate Disorder); CAQ (Committed Action Questionnaire); CAQ-8 (Committed Action Questionnaire – Short Form); CPVI (Chronic Pain Values Inventory); PIPS (Psychological Inflexibility in Pain Scale); CFQ (Cognitive Fusion Questionnaire); IBSAAQ (Acceptance of Irritable Bowel Syndrome Questionnaire); CPAQ (Chronic Pain Acceptance Questionnaire); CPAQ-8 (Chronic Pain Acceptance Questionnaire – Short Form); K-BPRI (Korean Version of Brief Pain Response Inventory); BPCI-2 (Brief Pain Coping Inventory – 2); BPRI (Brief Pain Response Inventory); MSAQ (Multiple Sclerosis Acceptance Questionnaire); VT (Values Tracker); AAQ-II-P (Acceptance and Action Questionnaire II - Pain Version); CVD-AAQ (Cardiovascular Disease Acceptance and Action Questionnaire); TAQ (Tinnitus Acceptance Questionnaire); ChCAQ-8 (Chinese Version of the eight item Committed Action Questionnaire); SEQ (Self-Experiences Questionnaire); MS (Multiple Sclerosis)**

Table 2.2

| Quality Criteria | 1 Int-Consist Rel | 2 T/RT Rel | 4 Cons Valid | 5 Cont Valid | 6 Crit Valid | 8 Scale Use | 9 Samp size | 10 Samp Rep | 11 Implications | 12 Conc in line with data | 13 Limits outlined |
|---|----------------------------------|---------------------------|-----------------------------|-----------------------------|-----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|--|-----------------------------------|
| Åkerblom <i>et al.</i> (2017) | + | n/a | ++ | ++ | ++ | + | - | - | + | + | + |
| Åkerblom <i>et al.</i> (2016) | ++ | n/a | - | ++ | ++ | + | - | + | ++ | ++ | ++ |
| Bailey (2016) | ++ | n/a | - | - | - | - | - | - | ++ | + | ++ |
| Barke <i>et al.</i> (2015) | ++ | n/a | ++ | ++ | ++ | + | - | - | + | + | ++ |
| Dionne <i>et al.</i> (2016) | n/a | n/a | ++ | + | ++ | ++ | - | - | ++ | ++ | ++ |
| Ferreira <i>et al.</i> (2013) | ++ | ++ | ++ | + | + | - | - | + | - | + | ++ |
| Fish <i>et al.</i> (2010) | ++ | n/a | - | - | ++ | - | - | ++ | - | + | ++ |
| Fish <i>et al.</i> (2013) | ++ | ++ | ++ | - | ++ | - | - | - | ++ | ++ | ++ |
| Gagnon <i>et al.</i> (2017) | ++ | n/a | ++ | ++ | ++ | - | - | + | + | ++ | ++ |
| Gillanders <i>et al.</i> (2014) (Sample 5) | ++ | n/a | ++ | + | ++ | ++ | - | + | ++ | ++ | ++ |
| Han <i>et al.</i> (2017) | ++ | ++ | - | + | - | - | ++ | - | + | + | ++ |
| Lundgren <i>et al.</i> (2012) (Study 1) | n/a | n/a | - | - | - | - | - | - | - | - | + |
| McCracken & Vowles (2007) | + | n/a | + | + | ++ | - | - | - | ++ | + | ++ |
| McCracken (2013) | ++ | n/a | + | ++ | - | + | ++ | - | ++ | ++ | ++ |
| McCracken <i>et al.</i> (2010) | ++ | n/a | - | + | - | ++ | - | - | - | + | ++ |
| McCracken <i>et al.</i> (2014) | ++ | n/a | - | - | + | - | - | - | + | + | ++ |
| McCracken <i>et al.</i> (2015) | ++ | n/a | ++ | - | ++ | + | - | - | ++ | + | ++ |
| Pakenham & Fleming (2011) | n/a | n/a | ++ | + | + | - | - | - | ++ | + | + |
| Pielech <i>et al.</i> (2016) | n/a | n/a | ++ | - | - | ++ | - | - | + | + | ++ |
| Reneman <i>et al.</i> (2014) | ++ | n/a | ++ | - | - | - | - | - | ++ | + | + |

| Quality Criteria | 1 Int-Consist Rel | 2 T/RT Rel | 4 Cons Valid | 5 Cont Valid | 6 Crit Valid | 8 Scale Use | 9 Samp size | 10 Samp Rep | 11 Implications | 12 Conc in line with data | 13 Limits outlined |
|---------------------------------|----------------------------------|---------------------------|-----------------------------|-----------------------------|-----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|--|-----------------------------------|
| Rodero <i>et al.</i> (2013) | ++ | ++ | + | ++ | ++ | - | + | - | + | + | ++ |
| Spatola <i>et al.</i> (2014) | ++ | ++ | ++ | + | ++ | - | - | - | ++ | ++ | + |
| Trompetter <i>et al.</i> (2014) | ++ | n/a | - | + | - | - | - | - | ++ | ++ | ++ |
| Weise <i>et al.</i> (2013) | n/a | n/a | n/a | n/a | n/a | + | - | - | ++ | ++ | ++ |
| Wicksell <i>et al.</i> (2009) | ++ | n/a | - | - | + | - | ++ | ++ | ++ | ++ | + |
| Wicksell <i>et al.</i> (2008) | n/a | n/a | - | - | - | - | - | - | ++ | - | ++ |
| Wicksell <i>et al.</i> (2010) | n/a | n/a | ++ | - | ++ | - | - | + | ++ | + | ++ |
| Wong <i>et al.</i> (2016) | ++ | n/a | - | ++ | ++ | + | - | - | ++ | ++ | ++ |
| Yu <i>et al.</i> (2016) | ++ | n/a | ++ | + | + | - | - | ++ | ++ | ++ | ++ |
| Yu <i>et al.</i> (2017) | + | n/a | - | - | - | - | - | - | + | + | ++ |

Table 2.2 – Quality assessment of included studies. ++ (well covered); + (adequately covered); - (poorly covered); n/a (not applicable).

Quality Criteria in full are: 1 (reliability – Internal Consistency), 2 (Reliability – Test-retest), 3 (Reliability – Overall*), 4 (Validity – Construct), 5 (Validity – Content), 6 (Validity – Criterion), 7 (Validity – overall*), 8 (Scale Usability), 9 (Sample Size), 10 (Sample Representativeness), 11 (Study Implications Defined), 12 (Conclusions follow on from data), 13 (Limitations of study outlined).

* Please note it was decided not to include 'Reliability – Overall' and 'Validity – Overall' within the reporting of quality criteria as these were formed from previous scores and do not represent a quality criteria in its own right.

Table 2.3

| Measure | Population Specific? | Population Validated in | Language | Alpha Level | Test-retest Reliability | Construct Validity | Criterion Validity | Content Validity | Length | Easy to use? |
|---------|----------------------|-------------------------|----------|-------------|-------------------------|--------------------|--------------------|------------------|--------|--------------|
| BPRI | Yes | Chronic Pain | Korean | ✓ (0.82) | ✓ (0.75) | ✗ | ✗ | ✓ | 15 | n.r. |
| | | Chronic Pain | English | ✓ (0.84) | ✗ | ✓ | ✗ | ✗ | 15 | n.r. |
| BPCI-2 | Yes | Chronic Pain | English | ✗ | ✗ | ✓ | ✓ | ✓ | 19 | n.r. |
| CVD-AAQ | Yes | CVD | Italian | ✗ (0.79) | ✓ (0.90) | ✓ | ✓ | ✓ | 7 | n.r. |
| PIPS | Yes | Chronic Pain | Swedish | ✓ (0.89) | ✗ | ✗ | ✗ | ✗ | 16 | n.r. |
| | | Chronic Pain | Swedish | ✗ | ✗ | ✗ | ✓ | ✓ | 12 | n.r. |
| | | Fibromyalgia | Spanish | ✓ (0.90) | ✓ (0.97) | ✓ | ✓ | ✓ | 12 | n.r. |
| | | Chronic Pain | German | ✗ (0.78) | ✗ | ✗ | ✓ | ✓ | 11 | n.r. |
| | | Chronic Pain | Dutch | ✓ (0.88) | ✗ | ✓ | ✗ | ✓ | 12 | n.r. |

Table 2.3 – Measures of Psychological Flexibility/Inflexibility

Abbreviations: BPRI (Brief Pain Response Inventory); BPCI-2 (Brief Pain Coping Inventory – 2); CVD-AAQ (Cardiovascular Disease Acceptance and Action Questionnaire); PIPS (Psychological Inflexibility in Pain Scale); n.r. (not reported).

Table 2.4

| Measure | Pop Specific? | Pop Validated in | Language | Alpha Level | Test/Re-test Reliability | Construct Validity | Criterion Validity | Content Validity | Length | Easy to use? |
|-------------------------|---------------|--------------------|----------|------------------|--------------------------|--------------------|--------------------|------------------|--------|--------------|
| Acceptance | | | | | | | | | | |
| CPAQ | Yes | Chronic Pain | English | ✓ (0.86-0.89) | ✗ | ✗ | ✓ | ✗ | 20 | n.r. |
| | | WAD | Swedish | ✓ (0.91) | ✗ | ✗ | ✓ | ✓ | 19 | n.r. |
| CPAQ-8 | Yes | Chronic Pain | English | ✓ (0.78-0.85) | ✓ (0.81) | ✗ | ✓ | ✗ | 8 | Yes |
| IBSAAQ | Yes | IBS | English | ✓ (0.89) | ✓ (0.93) | ✓ | ✓ | ✓ | 19 | n.r. |
| MSAQ | Yes | Multiple Sclerosis | English | ✓ (0.83) | ✗ | ✓ | ✓ | ✓ | 16 | n.r. |
| TAQ | Yes | Tinnitus | German | ✓ (0.86) | ✗ | ✗ | ✗ | ✗ | 12 | n.r. |
| Cognitive Fusion | | | | | | | | | | |
| CFQ | No | Chronic Pain | English | ✓ (0.87) | ✗ | ✗ | ✓ | ✗ | 13 | n.r. |
| | | MS | English | ✓ (0.93) | ✗ | ✗ | ✓ | ✓ | 7 | Yes |

| Measure | Pop Specific? | Pop Validated in | Language | Alpha Level | Test/Re-test Reliability | Construct Validity | Criterion Validity | Content Validity | Length | Easy to use? |
|-------------------------------|---------------|------------------|---------------------|------------------|--------------------------|--------------------|--------------------|------------------|--------|--------------|
| | | Chronic Pain | French | ✓ (0.94) | ✗ | ✓ | ✓ | ✓ | 7 | Yes |
| Committed Action | | | | | | | | | | |
| ChCAQ-8 | No | Chronic Pain | Chinese (Cantonese) | ✗ (0.75) | ✗ | ✗ | ✓ | ✓ | 8 | Yes |
| CAQ | No | Chronic Pain | Swedish | ✓ (0.89) | ✗ | ✓ | ✓ | ✓ | 18 | Yes |
| | | Chronic Pain | English | ✓ (0.90-0.91) | ✗ | ✓ | ✗ | ✓ | 18 | n.r. |
| | | Chronic Pain | English | ✓ (0.91) | ✗ | ✗ | ✗ | ✗ | 17 | n.r. |
| CAQ-8 | No | Chronic Pain | Swedish | ✓ (0.84) | ✗ | ✓ | ✓ | ✓ | 8 | Yes |
| | | Chronic Pain | English | ✓ (0.87) | ✗ | ✓ | ✓ | ✗ | 8 | n.r. |
| | | Chronic Pain | French | ✓ (0.86) | ✗ | ✓ | ✓ | ✓ | 8 | n.r. |
| Experiential Avoidance | | | | | | | | | | |
| AAQ-II-P | Yes | Chronic Pain | Dutch | ✓ (0.87) | ✗ | ✓ | ✗ | ✗ | 7 | n.r. |

| Measure | Pop Specific? | Pop Validated in | Language | Alpha Level | Test/Re-test Reliability | Construct Validity | Criterion Validity | Content Validity | Length | Easy to use? |
|--------------------------|---------------|------------------|-------------------------|-------------|--------------------------|--------------------|--------------------|------------------|---------|--------------|
| Self as Context | | | | | | | | | | |
| SEQ | No | Fibromyalgia | English | ✓ (0.94) | ✗ | ✓ | ✓ | ✗ | 11 | n.r. |
| | | Chronic Pain | English | ✓ (0.90) | ✗ | ✓ | ✓ | ✓ | 15 | n.r. |
| Values | | | | | | | | | | |
| Bull's-Eye Values Survey | No | Epilepsy | South African (Various) | ✗ | ✗ | ✗ | ✗ | ✗ | 3 parts | n.r. |
| CPVI | Yes | Chronic Pain | Swedish | ✗ | ✗ | ✓ | ✓ | ✓ | 12 | Yes |
| VT | No | Chronic Pain | English | ✗ | ✗ | ✗ | ✓ | ✗ | 2 | Yes |

Table 2.4 – Measures of individual elements of the hexaflex

Abbreviations: IBS (Irritable Bowel Syndrome); WAD (Whiplash Associate Disorder); CAQ (Committed Action Questionnaire); CAQ-8 (Committed Action Questionnaire – Short Form); CPVI (Chronic Pain Values Inventory); CFQ (Cognitive Fusion Questionnaire); IBSAAQ (Acceptance of Irritable Bowel Syndrome Questionnaire); CPAQ (Chronic Pain Acceptance Questionnaire); CPAQ-8 (Chronic Pain Acceptance Questionnaire – Short Form); MSAQ (Multiple Sclerosis Acceptance Questionnaire); VT (Values Tracker); AAQ-II-P (Acceptance and Action Questionnaire II - Pain Version); TAQ (Tinnitus Acceptance Questionnaire); ChCAQ-8 (Chinese Version of the eight item Committed Action Questionnaire); SEQ (Self-Experiences Questionnaire); MS (Multiple Sclerosis)

Discussion

This review investigated what assessment measures of Psychological Flexibility and its component parts have been developed and psychometrically assessed in a chronic health population. Thirty papers were identified that assessed the psychometric properties of measures designed to assess both Psychological Flexibility as a whole and the separate elements of the hexaflex. The reported reliability, validity and usability of these measures was discussed.

Four measures were identified that attempted to measure Psychological Flexibility as a whole; the BPRI, the BPCI-2, the CVD-AAQ and the PIPS. These measures were developed in a variety of languages and not all of them have been validated in a health population in English. This review found that the PIPS was the most often researched measure of Psychological Flexibility in a health population, and the psychometric properties of the Spanish version of the PIPS was the most well demonstrated (Rodero *et al.*, 2013). In the original study (Wicksell *et al.*, 2008), the PIPS was developed with the aim to measure multiple elements of the hexaflex. However, following factor analysis the scale was cut down in such a way that the remaining items only pertained to two parts of the hexaflex, avoidance and cognitive fusion. Despite this, the authors continue to describe this measure as a measure of Psychological Flexibility as a whole, and it is questionable whether this description is warranted due to the format of the final scale only assessing two elements of the hexaflex. Studies that follow on from this original study by other research teams do not often explicitly recognise this limitation of the PIPS, instead conceptualising it as only a measure of Psychological Flexibility (e.g. Rodero *et al.*, 2013). Due to this confusion surrounding what the PIPS actually measures, the

psychometric properties are difficult to assess as construct validity was often assessed against measures of Psychological Flexibility. This might suggest that the PIPS does measure Psychological Flexibility as a whole, however it might also mean that the PIPS is correlating with other measures of Psychological Flexibility as it is measuring some aspects of Psychological Flexibility, and therefore any correlation is indicating the closeness of these concepts. Future research could compare correlations of scores on the subscales of the PIPS with scores on measures designed to specifically measure avoidance and cognitive fusion and establish whether it is better correlated with these measures compared to measures of Psychological Flexibility. Of the English language measures of Psychological Flexibility identified in this review, the BPCI-2 has more psychometric properties established than the others. The BPCI-2 is population specific (chronic pain) so cannot be used in other populations.

Overall this review identified that measures of Psychological Flexibility that are validated in health populations are limited, with those that were identified being specific to a set population, most of which were chronic pain. There are several newer measures of Psychological Flexibility (e.g. the compACT, Francis *et al.*, 2016; the MPFI, Rolffs *et al.*, 2016) which aim to measure all elements of the hexaflex that make up Psychological Flexibility. These have had their psychometric properties assessed and established in other populations (Francis *et al.*, 2016; Rolffs *et al.*, 2016), but not explicitly in chronic ill health populations. Much research looking at the effectiveness of interventions based on ACT in health conditions assess changes in Psychological Flexibility using measures that have not been explicitly validated in chronic ill health populations (e.g. Feros *et al.*, 2013) such as the AAQ-II.

This review also identified scales that aimed to measure specific elements of the hexaflex. Measures for acceptance, cognitive fusion, committed action, experiential avoidance, self as context and values were identified. Some of these concepts are opposite points of the hexaflex, such as experiential avoidance and acceptance, **whilst others such as 'values' could be measuring either 'defining valued directions' or a 'lack of values clarity/contact'.** Many measures suggest that both elements of Psychological Inflexibility and Psychological Flexibility can be assessed with one scale with extremes of scores denoting greater Psychological Flexibility/Inflexibility depending on how the scale is measured. Other authors, however, have found that Psychological Flexibility and Inflexibility are better understood as two distinct concepts and perhaps it is not possible to assume that individuals who score low on a measure of Psychological Flexibility are psychologically inflexible (Rolffs *et al.*, 2016). It is possible that this difference in findings across the literature is related to differences in the way these measures are assessed. Alternatively, it could suggest that the underlying processes driving aspects of Psychological Flexibility/Inflexibility (i.e. avoidance and acceptance) are different. Of the measures identified, only IBSSAQ has had all its psychometric properties assessed and rated as adequately covered in this review. This measure is specifically designed to measure acceptance in IBS sufferers and therefore, cannot be used in a diverse number of settings. Most measures did not discuss how usable they are, however the chCAQ-8, CPAQ, CPVI, CFQ, CAQ, CAQ-8, and the VT have all had their usability discussed, often in terms of the shortness of the scale decreasing the burden on participants (Pielech *et al.*, 2016) or accessibility of wording designed to make it more acceptable for use in a variety of settings (Gillanders *et al.*, 2014).

This review identified that many measures of Psychological Flexibility or its elements have been developed, but that their psychometric properties fail to be fully established. Clinical research is often using these measures in chronic health condition populations despite these measures not being fully validated (e.g. Wicksell *et al.*, 2010). As a wide range of measures were identified, with many having elements of psychometric properties being established, future research could focus on establishing the reliability and validity of these existing measures more fully, rather than the development of additional measures that are only partially validated. This would help to identify those measures that are more robust and those that do not stand up to increased scrutiny and therefore, identify any gaps where more improved measures are required before the development of novel measures. Test-retest reliability was the element of reliability most often not assessed and future research could aim to assess test-retest reliability in the measures identified in this review to attempt to fill this gap in the evidence base.

This review also found that samples tended to have a higher percentage of women in them. Some populations investigated are more likely to be diagnosed in women, for example women are ten times more likely to be diagnosed with Fibromyalgia (Chakrabarty & Zoorob, 2007). However, other populations such as IBS have identified less difference between genders with a female to male gender ratio of 1.67:1 found in one review (Lovell & Ford, 2012), suggesting that the samples used were biased towards women in their recruitment. Some research has demonstrated that there is a gender difference in some aspects of Psychological Flexibility with men scoring significantly higher than women (Reneman *et al.*, 2014). Future

research could attempt to assess Psychological Flexibility in populations that have a higher male proportion such as some cancers in order to assess whether these measures are valid and reliable in male populations as well.

The samples were also more likely to be focussed on chronic pain populations, even when assessing measures that are designed to be non-population specific (e.g. Åkerblom *et al.*, 2016). This limits the generalisability of the literature identified as a whole, as it is difficult to ascertain whether these measures are appropriate to use in a range of chronic health conditions or purely appropriate for a chronic pain population. Many of the measures assessed in other populations, such as the MSAQ or IBSAAQ are population specific (MS and IBS respectively) and therefore, cannot be applied to other health populations. Future research could assess the generic measures of both Psychological Flexibility and elements of the hexaflex identified in this review in more diverse ill health populations to establish the applicability of these in different populations and to attempt to establish whether the pattern of responding to these generic measures differ depending on the health population under investigation.

This review also aimed to assess the usability of the measures identified in order to make recommendations on their usefulness for clinical settings. Very few papers discussed the usability of the scale, either for the clinician, or even more rarely for the participant. No papers explicitly identified whether their scale was free to use, however, some authors did state that the measure was available from the author (McCracken & Vowles, 2007), or available on a website (Gillanders *et al.*, 2014), however it was not clear whether this meant the scale was free to use. This is of

particular relevance to publicly funded healthcare contexts, such as the UK National Health Service (NHS) where resources are limited and scales that are accessible free of charge are important. Future research looking at developing new scales, or further evaluating the psychometric properties of existing ones should include in their description of the scale information that allows the reader to readily establish how easy the scale is to administer, score and interpret, the burden it creates for the participant and whether there is a cost to using it. This information, in addition to the psychometric evaluation of measures would make it much easier for busy researchers and clinicians to quickly identify the most suitable measure for their context.

The concept of Psychological Flexibility is one that is still being developed and added to, with some researchers more recently suggesting a model of three overarching themes that combines elements of the hexaflex in to subgroups (Hayes *et al.*, 2010). This ever-changing nature of the concept of Psychological Flexibility, whilst in some ways can be thought of as a strength of the model, presents significant challenges when trying to apply traditional psychometric rigour to these concepts. A second difficulty is that the processes underlying Psychological Flexibility (elements of the hexaflex) are all interlinked and together form the construct of Psychological Flexibility. There has been controversy in the literature surrounding whether measures of Psychological Flexibility need to explicitly measure all elements of the hexaflex, or to measure it in a way that adequately captures the overarching idea of Psychological Flexibility and does not need to necessarily explicitly measure each component part (Rolffs *et al.*, 2016). Within psychometric traditions, construct validity, by its very nature, is assessing whether a measure

truly measures what it is aiming to measure, and it is assumed that the concept that we are trying to measure is a concrete construct and psychometric research attempts to find the optimal way of measuring it. This leads to a query of whether psychometric measures are the best way of measuring ACT processes as it does not appear to fit with the core principles and values of the ACT model.

In describing this tension between psychometric science and the a-ontological position of contextual behavioural science, some authors (Jeffcoat *et al.*, 2015) have proposed a metaphor of them being like two different peoples, speaking different languages. In this metaphor, it is not that the concepts being described by the two peoples are incompatible, rather, that each need to be able to speak and understand **each other's languages**. **This metaphor could be extended, as in reality, it is not the two different 'languages' alone that cause difficulty in interpreting the** reliability and validity of measures of Psychological Flexibility, it is that the philosophical science underpinning the theory of Psychological Flexibility does not view the concepts as essential or absolute. Instead, theories are judged in relation to how workable or useful they are in producing effective behavioural actions, rather than how well they correspond with an external ontological reality. Language has many diverse and nuanced elements as it develops in a context. This can be seen in countries having multiple names for similar things, often in response to the usefulness of being able to delineate between finer differences in concepts. A good example of this could be to think about rain. Rain in its most basic form is water falling from the sky, and to teach another individual this word, one could point to the water falling from the sky and call it rain. However, within a language there may be many words or phrases for rain such as; **'bucketing it down', 'drizzle', 'mizzle' and**

'pouring'. Therefore, by naming it solely as rain, the complexity of the language is missed. In addition, those only taught the word rain are unlikely to be able to understand conversations about the weather when a plethora of words to describe the water falling from the sky are commonly used. In a similar way, by using a psychometric method to conceptualise Psychological Flexibility this results in a reduction of a complex, nuanced and ever-changing concept to specific concrete constructs, which could be argued to no longer represent the original concept. In addition, when concrete measures are used, but discussions within the contextual science community continue to include the many ways in which Psychological Flexibility is conceptualised, individuals from other areas of science may be excluded from the contextual science community as the complexity could be overwhelming and confusing if it is presented elsewhere as concrete. Therefore, whether psychometric scales are the best way to measure ACT concepts needs to be investigated with perhaps the use of other methodology such as individualised feedback within a qualitative research framework being developed as a more contextually-based alternative.

This review has several limitations. As it aimed to assess only measures that had been explicitly validated in health populations, some measures found in this review may have been previously more fully validated in other populations. This is of particular relevance to content validity of a scale, which may have been assessed in other populations previously. This could mean that the current review has concluded that content validity has not been assessed, despite there being evidence for content validity elsewhere. However, this review would have identified if content validity was explicitly assessed in a health population which is an important finding

for clinicians and researchers attempting to decide what measure to use for evaluating Psychological Flexibility and its components within in a physical health population. Three papers were not available, two of these were due to them being theses that were not available online and could not be sourced directly from the authors and the final one was in a language that translation could not be sought for. It was difficult to find an explicit definition of what a chronic ill health condition was, resulting in the authors having to discuss queries of inclusion/exclusion and relying on a consensus view which may have resulted in a bias. For example, some papers were not included as it was felt that they were not a chronic ill health condition, such as papers using a traumatic brain injury population, as it was felt that as this population represents individuals who may (or may not) recover to a premorbid functioning level as well as individuals who may be left with chronic disability that it was not possible to establish the chronic nature of these conditions. This could limit the review as not all physical ill health conditions were included making this review limited to chronic ill health conditions only. This review also assessed specific elements of validity and reliability which were described by previous research as the elements that are core to the assessment of the psychometric properties (Saane *et al.*, 2003). However, this means that other elements such as incremental validity or the factor analysis of scales was not assessed. Although this review did not automatically exclude any papers on the basis of language, very few papers were identified that were in other languages. This could be because search methods were limited to databases that primarily included English language journals which may have biased the review.

Conclusion

This review aimed to assess what measures of Psychological Flexibility and its component parts have been assessed as reliable and valid in chronic health populations. Only two measures of Psychological Flexibility were assessed as having all its psychometric properties as confirmed, the Spanish version of the PIPS (which is designed for people with chronic pain only) and the Italian CVD-AAQ (which is designed for use with people with CVD only). Of the measures of the individual elements of the hexaflex, only the IBSAAQ, which is designed to measure acceptance in patients with IBS, had confirmed psychometric properties across the board. This review identified that many measures have not been fully validated in a chronic ill health population. In relation to measures of Psychological Flexibility as a whole, this review suggested that measures that are generic and not population specific need to be developed and perhaps existing measures such as the compACT (Francis *et al.*, 2016) and MPFI (Rolffs *et al.*, 2016) that have been validated in other populations could be assessed with regards to their psychometric properties in an ill health population. With regards to measures of individual elements of the hexaflex the review suggested that the focus for future research might be better placed on further validation of existing measures with the aim of attempting to develop a more robustly assessed measure, rather than the development of additional measures.

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Appendices

Appendix 2.A

Submission guidelines for Assessment, taken from <https://uk.sagepub.com/en-gb/eur/assessment/journal201629#submission-guidelines> (accessed on 09/04/18).

The editor invites high quality manuscripts covering a broad range of topics and techniques in the area of psychological assessment. These may include empirical studies of assessment of personality, psychopathology, cognitive functions or behavior, articles dealing with general methodological or psychometric topics relevant to assessment, or comprehensive literature reviews in any of these areas. This journal encourages submissions evaluating a) new assessment methodologies and techniques for both researchers and practitioners, b) how assessment methods and research informs understanding of major issues in clinical psychology such as the structure, classification, and mechanisms of psychopathology, and c) multi-method assessment research and the integration of assessment methods in research and practice. Additionally, the journal encourages submissions introducing useful, novel, and non-redundant instruments or demonstrating how existing instruments have applicability in new research or applied contexts. All submissions should provide strong rationales for their efforts and articulate important implications for assessment science and/or practice

Research participants may represent both clinical and nonclinical populations.

In general, regular articles should not exceed 30 pages of text, excluding Title Page, Abstract, Tables, Figures, Footnotes and Reference list.

Authors submitting manuscripts to the journal should not simultaneously submit them to another journal, nor should manuscripts have been published elsewhere, including the World Wide Web, in substantially similar form or with substantially similar content.

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Manuscript Submission:

Manuscripts must be submitted in Microsoft Word or Rich Text Format (rtf) electronically at <https://mc.manuscriptcentral.com/asmnt>. Figures may be submitted using any of the formats listed below. If requesting a masked blind review, please ensure that both a manuscript file with no identifying author information and a separate title page with author details are included in your submission. Questions should be directed to the ASSESSMENT Editorial Office by email: assessment.editorial@gmail.com.

If you or your funder wish your article to be freely available online to nonsubscribers immediately upon publication (gold open access), you can opt for it to be included in SAGE Choice, subject to the payment of a publication fee. The manuscript submission and peer review procedure is unchanged. On acceptance of your article, you will be asked to let SAGE know directly if you are choosing SAGE Choice. To check journal eligibility and the publication fee, please visit [SAGE Choice](#). For more information on open access options and compliance at SAGE, including self/author archiving deposits (green open access) visit [SAGE Publishing Policies](#) on our Journal Author Gateway.

Preparation of Manuscripts:

Authors should carefully prepare their manuscripts in accordance with the following instructions.

Authors should use the Publication Manual of the American Psychological Association (6th edition, 2009) as a guide for preparing manuscripts for submission. All manuscript pages, including reference lists and tables, must be typed double-spaced.

The first page of the paper (the title page) should contain the article title, the names and affiliations of all authors, authors' notes or acknowledgments, and the names and complete mailing addresses of the corresponding author. If requesting a masked blind review, the first page should contain only the article title and the title page should be uploaded as a separate document.

The second page should contain an abstract of no more than 150 words and five to seven keywords that will be published following the abstract.

The following sections should be prepared as indicated:

Tables. Each table should be fully titled, double-spaced on a separate page, and placed at the end of the manuscript. Tables should be numbered consecutively with Arabic numerals. Footnotes to tables should be identified with superscript lowercase letters and placed at the bottom of the table. All tables should be referred to in the text.

Figures. Electronic copies of figures can be submitted in one of the following file formats: TIFF, EPS, JPEG, or PDF. All figures should be referred to in text. Each figure should appear on a separate page at the end of the manuscript but before the tables, and all titles should appear on a single, separate page.

Endnotes. Notes should appear on a separate page before the References section. Notes should be numbered consecutively and each endnote should be referred to in text with a corresponding superscript number.

References. Text citations and references should follow the style of the Publication Manual of the American Psychological Association (6th edition, 2009).

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Authors are encouraged to consider submitting ancillary analyses and other relevant information as electronic supplements. Such supplements should be uploaded using the supplemental files tag in Scholar One. Only doc, docx., and .pdf files are accepted for published electronic supplements. Electronic supplemental information for published manuscripts should take the form of Tables and Figures, formatted and annotated just

as they would be for a manuscript, but numbered as Table S1, S2, S3, etc. and Figure S1, S2, S3 etc. Article text should refer to material in electronic supplements as appropriate, just as they would a table or figure in the published article.

Supplementary Material

Supplementary Material S2.1

Search criteria used for each database

PsychInfo

| Search Number | Keyword(s) |
|---------------|--|
| 1 | "Acceptance and Commitment Therapy"* OR "Psychological Flexibility" OR "Psychological Inflexibility" OR "Psychological Rigidity" |
| 2 | "Measurement"*+ OR "Test Validity"*+ OR "Test Reliability"*+ |
| 3 (Final) | "Search 1" AND "Search 2" |

*Keyword mapped to subject heading

+ EXPLODE function used on keyword

"" Each individual keyword

MedLine

| Search Number | Keyword(s) |
|---------------|---|
| 1 | "Acceptance and Commitment Therapy"* OR "Psychological Flexibility" OR "Psychological Inflexibility" OR "Psychological Rigidity" |
| 2 | "Psychological Tests"*+ OR "Reproducibility of Results"*+ OR "Sensitivity and Specificity"*+ OR "Social Validity, Research"* OR "Validation Studies"* |
| 3 (Final) | "Search 1" AND "Search 2" |

*Keyword mapped to subject heading

+ EXPLODE function used on keyword

Psychological Sciences and Behavioural Collection

| Search Number | Keyword(s) |
|---------------|---|
| 1 | "Acceptance and Commitment Therapy" OR "Psychological Flexibility" OR "Psychological Inflexibility" OR "Psychological Rigidity" |
| 2 | "Measurement" OR "Validity" OR "Reliability" |
| 3 (Final) | "Search 1" AND "Search 2" |

*Keyword mapped to subject heading

+ EXPLODE function used on keyword

CINAHL

| Search Number | Keyword(s) |
|---------------|---|
| 1 | "Acceptance and Commitment Therapy"* OR "Psychological Flexibility" OR "Psychological Inflexibility" OR "Psychological Rigidity" |
| 2 | "Psychological Tests")*+ OR "Research Measurement"*+ OR "Measurement Issues and Assessments"*+ OR "Measurement Instruments"*+ OR "Research Methodology"*+ |
| 3 (Final) | "Search 1" AND "Search 2" |

*Keyword mapped to subject heading

+ EXPLODE function used on keyword

CENTRAL

Keyword "Psychological Flexibility" used and all records with this keyword searched.

Google Scholar

Keywords: "Psychological Flexibility" AND "Measurement". First ten pages (100 records) searched.

Quality Criteria for Systematic Review

Version 3

Reliability and Validity of psychometric measures of Psychological Flexibility for use in a health population – a systematic review.

| | Quality Criteria |
|----|------------------------------------|
| 1 | Reliability – Internal consistency |
| 2 | Reliability – Test-retest |
| 3 | Reliability - overall |
| 4 | Validity – Construct |
| 5 | Validity – Content |
| 6 | Validity - Criterion |
| 7 | Validity - overall |
| 8 | Scale Usability |
| 9 | Sample size |
| 10 | Sample representativeness |
| 11 | Study implications defined |
| 12 | Conclusions follow from data |
| 13 | Limitations of study outlined |

1 – Reliability – Internal consistency – the consistency of results across items within a test.

| | |
|----------------------|--|
| Well covered | Reports assessment of internal consistency with an appropriate statistical correlational technique AND Interprets this accurately throughout the paper – e.g. using pre-established criteria for what level the correlation is at, discusses the measure within the limits of the correlation strength (i.e. does not over extend in conclusions). |
| Adequately addressed | Reports assessment internal consistency with an appropriate statistical correlational technique BUT Does not interpret this correlational technique accurately using accepted criteria, or makes conclusions based on the outcome of statistical testing that are beyond the scope of their findings. |
| Poorly addressed | Study aims to assess reliability in its key aims, but does not mention or discuss internal consistency. OR Discusses internal consistency, but does not report assessing it using an appropriate statistical method or does not report the outcomes of any statistical methods proposed/used. |
| Not applicable | Study does not aim to assess reliability in its key aims |
| Notes | |

2 – Reliability – Test-retest - The degree to which test scores are consistent from one testing to another.

| | |
|----------------------|---|
| Well covered | Reports assessment of test-retest reliability with an appropriate statistical correlational technique AND Interprets this accurately throughout the paper – e.g. using pre-established criteria for what level the correlation is at, discusses the measure within the limits of the correlation strength (i.e. does not over extend in conclusions). |
| Adequately addressed | Reports assessment test-retest reliability with an appropriate statistical correlational technique BUT Does not interpret this correlational technique accurately using accepted criteria, or makes conclusions based on the outcome of statistical testing that are beyond the scope of their findings. |
| Poorly addressed | Study aims to assess reliability in its key aims, but does not mention or discuss inter-rater reliability. OR Discusses test-retest reliability, but does not report assessing it |

| | |
|----------------|---|
| | using an appropriate statistical method or does not report the outcomes of any statistical methods proposed/used. |
| Not applicable | Study does not aim to assess test-retest reliability in its key aims |
| Notes | |

3 – Reliability – Overall.

| | |
|----------------------|---|
| Well covered | The authors report both forms of reliability assessed above and the paper was graded as “well covered” in both. |
| Adequately addressed | The authors report both forms of reliability assessed above as adequately addressed |
| Poorly addressed | The authors only report one form of reliability regardless of how well they have reported it OR The authors report more than one form of reliability but both were judged to be “poorly addressed” or only one was “adequately addressed” |
| Not applicable | Study does not aim to assess reliability in its key aims |
| Notes | Note – if the paper meets two criteria, award the higher option. |

4 – Validity – Construct – The extent to which the test measures what it says is measures

| | |
|----------------------|---|
| Well covered | Reports assessment of construct validity. This could be through convergent validity (how correlated the tool is with another tool that purports to measure the same thing) or discriminant validity (how uncorrelated the tool is with another tool that purports to measure a different or similar construct). Appropriate statistical testing should be used. AND Interprets this accurately throughout the paper – e.g. using pre-established criteria for what level the correlation is at, discusses the measure within the limits of the correlation strength (i.e. does not over extend in conclusions). |
| Adequately addressed | Reports assessment of construct validity. This could be through convergent validity (how correlated the tool is with another tool that purports to measure the same thing) or discriminant validity (how uncorrelated the tool is with another tool that purports to measure a different or similar construct). Appropriate statistical testing should be used. BUT Does not interpret this technique accurately using accepted criteria, or makes conclusions based on the outcome of statistical testing that are beyond the scope of their findings. |

| | |
|------------------|--|
| Poorly addressed | Study aims to assess validity in its key aims, but does not mention or discuss construct validity. OR Discusses construct validity, but does not report assessing it using an appropriate statistical method or does not report the outcomes of any statistical methods proposed/used. |
| Not applicable | Study does not aim to assess validity in its key aims |
| Notes | |

5 – Validity – Content - how well does the test cover all aspects of what it is trying to measure

| | |
|----------------------|--|
| Well covered | Reports that the measure was developed in a way that makes it possible for content validity to be assessed; including but not limited to; taking questions from other relevant measures, using experts (professional and by experience) to help develop questions, focus groups of appropriate individuals to generate questions. AND Reports assessing face validity of the measure in some way (e.g. would a non-expert observer know what the questionnaire is measuring from reading it). N.B. – in some cases it could be argued that face validity is not appropriate (e.g. if the test developers do not want the measure to be identifiable to someone filling in the measure), therefore if the authors specifically argue against the need for face validity, “well covered” can be given based on the first criterion alone. |
| Adequately addressed | Reports that the measure was developed in a way that makes it possible for content validity to be assessed; including but not limited to; taking questions from other relevant measures, using experts (professional and by experience) to help develop questions, focus groups of appropriate individuals to generate questions. OR Reports assessing face validity of the measure in some way (e.g. would a non-expert observer know what the questionnaire is measuring from reading it). |
| Poorly addressed | Study aims to assess validity in its key aims, but does not mention or discuss content or face validity. OR Discusses content or face validity, but does not report assessing it a way that allows the reader to make conclusions about the scales content or face validity. |
| Not applicable | Study does not aim to assess validity in its key aims |

| | |
|-------|--|
| Notes | Face validity is a related concept that is not technically part of content validity. However, for the purposes of keeping the number of criterion to a manageable level, face validity is being included under the umbrella of content validity. |
|-------|--|

6 – Validity – Criterion – does the scale correlate with measures of constructs that are seen as relative to the construct under investigation?

| | |
|----------------------|--|
| Well covered | <p>Reports assessment of criterion validity with either concurrent validity (does it correlate with a related construct at the time of testing) or predictive validity (do scores on the measure at time point one correlate with scores on another measure of a related construct at time two) using an appropriate statistical correlational technique</p> <p>AND</p> <p>Interprets this accurately throughout the paper – e.g. using pre-established criteria for what level the correlation is at, discusses the measure within the limits of the correlation strength (i.e. does not over extend in conclusions).</p> |
| Adequately addressed | <p>Reports assessment of criterion validity with either concurrent validity (does it correlate with a related construct at the time of testing) or predictive validity (do scores on the measure at time point one correlate with scores on another measure of a related construct at time two) using an appropriate statistical correlational technique</p> <p>BUT</p> <p>Does not interpret this correlational technique accurately using accepted criteria, or makes conclusions based on the outcome of statistical testing that are beyond the scope of their findings.</p> |
| Poorly addressed | <p>Study aims to assess validity in its key aims, but does not mention or discuss criterion validity</p> <p>OR</p> <p>Discusses criterion validity (including concurrent or predictive), but does not report assessing it using an appropriate statistical method or does not report the outcomes of any statistical methods proposed/used.</p> |
| Not applicable | Study does not aim to assess validity in its key aims |
| Notes | Note regarding predictive validity. Technically predictive validity needs to occur over two timepoints, for example construct X at timepoint 1 predicts construct Y at timepoint 2. However, in reality, predictive validity is often claimed from data collected at one timepoint. A paper that claims predictive validity from data at one timepoint can still be awarded “well covered” on criterion validity if they meet the criteria through concurrent validity. If the paper considers predictive validity alone from data collected |

| | |
|--|---|
| | <p>from one timepoint alone, the quality assessor needs to decide whether it was sufficiently well interpreted to be allowed a “well covered” rating or whether “adequately addressed” is better. To be well covered the authors should report clear reasoning for why (based on their theoretical model, or previous literature) they are able to claim that one construct is predicting another. Adequately addressed would be assigned if the authors do not justify their claiming predictive validity from data collected at one timepoint alone.</p> |
|--|---|

7 – Validity – Overall

| | |
|----------------------|---|
| Well covered | The authors report all three forms of validity assessed above and the paper was graded as “well covered” in at least two, with the third graded as adequately addressed if applicable. |
| Adequately addressed | <p>The authors must have reported on construct validity at “well covered” or “adequately addressed” to get this grade in addition to:</p> <p>The other two forms at “adequately addressed” or “well covered”</p> <p>OR</p> <p>One other form only at “well covered”</p> <p>OR</p> <p>One other form at “well covered” and the other at “poorly covered”</p> |
| Poorly addressed | <p>The authors only report one form of validity regardless of how well they have reported it</p> <p>OR</p> <p>The authors report more than one form of validity but all were judged to be “poorly addressed” or “adequately addressed”</p> <p>OR</p> <p>The paper was judged to have “poorly addressed” the construct validity.</p> |
| Not applicable | Study does not aim to assess validity in its key aims |
| Notes | Note – if the paper meets two criteria, award the higher option. |

8 – Scale Usability

| | |
|--------------|---|
| Well covered | The authors report detailed aspects of the scale other than reliability and validity that allow the reader to make conclusions about scale usability. For example, whether the scale is short, free to use, easy to understand, easy to score, easy to interpret, whether the authors have gained feedback from their participants regarding usability... |
| Adequately | The authors make some reference to scale usability, but do not |

| | |
|------------------|--|
| addressed | go into much detail or provide many examples of how they are demonstrating scale usability. |
| Poorly addressed | The authors do not address aspects of scale usability OR The authors only say “the scale is easy to use” or something similar without discussing how the scale is easy to use. |
| Not applicable | The authors have stated that scale usability was well established in a previous paper that investigated the same scale and referenced this appropriately. |
| Notes | |

9 – Sample size

| | |
|----------------------|--|
| Well covered | Sample size required was reported as being assessed <i>a priori</i> and this sample size was reached |
| Adequately addressed | Sample size required was reported as being assessed <i>a priori</i> and this sample size was not reached, but conclusions of the paper were discussed in light of this. |
| Poorly addressed | Sample size was not discussed as being assessed <i>a priori</i> using a statistical method OR Sample size required was reported as being assessed <i>a priori</i> and this sample size was not reached and the authors do not discuss this or interpret the conclusions of the paper appropriately given this. |
| Not applicable | No sample was used |
| Notes | |

10 – Sample representativeness

| | |
|----------------------|--|
| Well covered | The study reports using sampling methods that would lead to a representative sample (e.g. methods that would not bias the population in any way, such as using only university students, or using a convenience sample) AND The study reports the variability of the sample on key demographic variables (e.g. age, ethnicity, education status), and, if relevant, discusses the in relation to the conclusions of the study. |
| Adequately addressed | The study reports using sampling methods that would lead to a representative sample (e.g. methods that would not bias the population in any way, such as using only university students, or using a convenience sample) BUT Does not report the variability of the sample on key |

| | |
|------------------|--|
| | demographic variables (e.g. age, ethnicity, education status). |
| Poorly addressed | The study does not report it's sampling methods or the variability of the sample on key demographic variables OR The sampling methods are such that they create a bias in the sample e.g. using one population type only, or using a convenience sample. |
| Not applicable | No sample was used |
| Notes | |

11 – Study implications defined

| | |
|----------------------|---|
| Well covered | The implications of the results of the study for the wider research base and the population under study are clearly described and discussed. AND This follows clearly on from the literature introduced in the introduction AND Future possible research avenues are discussed (especially ways to move the science forward) |
| Adequately addressed | The implications of the results of the study for the wider research base and the population under study are adequately described and some discussion of this occurs. This is not well linked with the literature introduced in the introduction however. AND/OR Some future research avenues are suggested, but these are limited to how to improve the current study if it were redone and not suggestions of future research that would move the science forward. |
| Poorly addressed | The implications of the study for the wider research base or the population under study are not adequately described (briefly mentioned, without reference to literature introduced in the introduction) or not discussed. AND No future research avenues are suggested. |
| Not applicable | |
| Notes | There is no “not applicable” option. |

12 – Conclusions follow from data

| | |
|--------------|--|
| Well covered | Conclusions are fully in line with the actual results of the paper. They do not over extend in any way. All data is discussed equally with no suppression or downplaying results/data that did not fall |
|--------------|--|

| | |
|----------------------|--|
| | in line with the proposed model. |
| Adequately addressed | <p>Conclusions are, for the most part, in line with the actual results of the paper. The authors may suggest conclusions that seem a bit beyond the results of the paper, however this is done in a way that is clear what conclusions are from the results and which are more hypothetical ways the results could be interpreted, and the authors clearly acknowledge this.</p> <p>Some overenthusiastic interpretation of results is present, but this is not in a way that drastically changes the overall conclusions of the paper.</p> <p>There is some presence of suppression or downplaying results/data that did not fall in line with the proposed model.</p> |
| Poorly addressed | Conclusions do not seem in line with the data, or are very over extended from the actual data gathered. The authors do not discuss, or largely downplay/supress results/data that did not fall in line with the proposed model. |
| Not applicable | |
| Notes | There is no “not applicable” option. |

13 – Limitations of study outlined

| | |
|----------------------|--|
| Well covered | <p>The authors report the limitations of the study in clear detail including acknowledging weaknesses inherent in the methods they have used as well as limitations of the specific study.</p> <p>Examples include: acknowledging possible other conclusions for their results, discussing confounding/extraneous variables not assessed, identifying and discussing potential sources of bias (e.g. sampling bias).</p> |
| Adequately addressed | <p>The authors discuss limitations of the study in a broad sense, mentioning one or two forms of limitations inherent to their specific study, but not acknowledging other forms of limitations inherent to the methodology used.</p> <p>OR</p> <p>The authors have missed an important limitation or weakness of the study, but have discussed other forms of limitations well.</p> |
| Poorly addressed | The authors do not report limitations of their study. |
| Not applicable | |
| Notes | There is no “not applicable” option. |

Chapter 3 – Empirical Paper

Psychological Flexibility in Prostate Cancer

Written according to guidelines for the Journal of Contextual Behavioural Science

(See Appendix 3.A).

Lindsay-Jo Sevier-Guy^{ab1}, Caroline Sommerville^b, Nuno Ferreira^{a,2}, David Gillanders^a

^a School of Health and Social Science, University of Edinburgh

^bPsychology Department, NHS Fife

¹Corresponding Author (s1580020@sms.ed.ac.uk)

²Current Affiliation: School of Humanities and Social Sciences, University of Nicosia

Word Count: 6335

Abstract

Background: Individuals with cancer often experience fear that this cancer will get worse or return. Those with high levels of fear of recurrence experience greater psychological distress and poorer quality of life. Psychological Flexibility can be related to psychological distress and quality of life in cancer patients. How Psychological Flexibility might play a role in this relationship between fear of cancer recurrence and psychosocial outcomes of cancer has not been established previously.

Methods: Fear of recurrence and Psychological Flexibility are less researched in men with prostate cancer. Therefore, this cross-sectional study initially used multiple regression to establish whether Psychological Flexibility and fear of recurrence might explain variance in the outcome variables of psychological distress and quality of life. To establish whether Psychological Flexibility might have a role to play in the relationship between fear of recurrence and outcome variables, conditional process analysis was used to assess whether Psychological Flexibility mediates or moderates the relationship between fear of recurrence and the outcome variables.

Results: Psychological Flexibility was shown to significantly explain some of the variance in psychological distress and quality of life and appeared to be a stronger predictor of psychological distress than fear of recurrence. Fear of recurrence also significantly explained some of the variance in both outcome variables and was a stronger predictor of quality of life than Psychological Flexibility. The data revealed that there was evidence that Psychological Flexibility could be conceptualised both as a mediator or a moderator of the relationship between fear of recurrence and

psychological distress. For the relationship between fear of recurrence and quality of life, the data revealed there was only evidence for Psychological Flexibility acting as a moderator.

Conclusions: These findings suggest that Psychological Flexibility might be a useful treatment target, through interventions such as Acceptance and Commitment Therapy, to improve psychosocial outcomes in men with prostate cancer.

Keywords

Psychological Flexibility; Prostate Cancer; Quality of Life; Psychological Distress; Fear of Cancer Recurrence; Conditional Process Analysis.

Highlights

- Psychological Flexibility explains variance in psychosocial outcomes
- Fear of cancer recurrence explains variance in psychosocial outcomes
- Psychological Flexibility mediates fear of cancer recurrence and psychosocial outcomes
- Psychological Flexibility moderates between fear of cancer recurrence and distress

Introduction

Prostate cancer and Psychosocial Outcomes

National Institute for Health and Care Excellence (NICE) guidelines (2014) indicate that for men, prostate cancer is the most common form of cancer, accounting for 26% of all cancer diagnosed in men. Prostate Cancer impacts on psychosocial outcomes, including psychological distress, quality of life (QoL) and fear of cancer recurrence (FCR).

Psychological distress

Psychological Distress is defined differently throughout the cancer literature, however, the National Comprehensive Cancer Network (NCCN, 2013) definition is used most frequently:

"Distress is a multifactorial unpleasant emotional experience of a psychological (cognitive, behavioural, emotional), social, and/or spiritual nature that may interfere with the ability to cope effectively with cancer, its physical symptoms and its treatment. Distress extends along a continuum, ranging from common normal feelings of vulnerability, sadness, and fears, to problems that can become disabling, such as depression, anxiety, panic, social isolation, and existential and spiritual crisis"

(pg7)

Research shows that men with prostate cancer experience psychological distress (Balderson & Towell, 2003). There are many stages in the cancer journey where psychological distress can be experienced for men with prostate cancer (e.g.

diagnosis, decision making, treatment, recovery, survivorship) and research has shown that levels of distress experienced can fluctuate across these stages (Roth *et al.*, 1998) perhaps due to psychological demands differing at each stage (Hsiao *et al.*, 2011). Some studies indicate that psychological distress is lower in prostate cancer when compared to other cancers (Venderbos *et al.*, 2015), perhaps due to its higher survival rate compared to other forms of cancer (Cancer Research UK Website, accessed 14/11/16). However, reviews have demonstrated mixed findings (Sharpley *et al.*, 2008). The diversity of the findings might be explained by the way men display distress when they have prostate cancer. Mróz, Oliffe and Davison (2013) found that men with prostate cancer cope with the distress of having prostate cancer by using emotionally detached responses such as stoicism. Wall *et al.* (2013) conducted a qualitative study of men's experiences of their first year post diagnosis. The authors found that following a period of overt distress, men used avoidance strategies to cope with further distress such as playing down the role of the psychological impact of having a diagnosis of prostate cancer. Blank & Bellizzi (2006) showed that the mixed results when looking at the levels of psychological distress in men who have survived prostate cancer may be due to the different coping styles used, with escapist coping style being negatively correlated with happiness and positive affect. Therefore, it may be that research is underestimating the level of distress associated with prostate cancer, due to men using strategies to avoid their distress. Further research combining data from many studies found that psychological distress is associated with increased risk of mortality with higher levels of psychological distress being associated with higher levels of mortality (Batty *et al.*, 2017). This study found that this effect was true for prostate cancer even after elements such as age, education status, BMI, smoking and alcohol intake were

controlled for (Batty *et al.*, 2017). This highlights the importance of establishing what factors are related to psychological distress in men with prostate cancer.

Quality of Life

Similarly, the findings related to QoL in individuals with prostate cancer seem to be mixed, fluctuating depending on stage of cancer journey (Jeldres *et al.*, 2015; Drummond *et al.*, 2015). Katz (2007) found that QoL is affected, regardless of type of active treatment. Specifically, it was found that the effect of prostate cancer **treatment on a man's sexual functioning had the most significant impact on their** QoL (Katz, 2007). When looking across the whole cancer journey however, results are more mixed with certain stages of the prostate cancer journey being associated with lower QoL than others, for example, those who have undergone surgery tend to report lower QoL compared to those that are undergoing active surveillance (Jeldres *et al.*, 2015). Poorer QoL is associated with aspects of psychological distress such as depression (Saini *et al.*, 2013).

Fear of Cancer Recurrence

Individuals who have previously been diagnosed with prostate cancer or are currently diagnosed can suffer fear that this cancer will return (Mehta *et al.*, 2003). FCR can be a burden to individuals with prostate cancer before and after treatment (Mehta *et al.*, 2003). FCR has been assessed and identified across the prostate cancer journey, including before, during and after treatment (Hart *et al.*, 2008). High levels of FCR has also been shown to be related to both poorer QoL and higher psychological distress (Hart *et al.*, 2008; Bellizzi *et al.*, 2008). As with QoL and psychological distress in prostate cancer, the level of fear of recurrence can differ

depending on treatment, with men undergoing surgery reporting greater FCR than those on active surveillance (Matthew *et al.*, 2017).

Psychological Flexibility

Psychological Flexibility is an important part of psychological health and is defined by Kashdan (2010) as how well a person copes and adapts to varying psychological demands, applies mental resources flexibly, shifts their perspective depending on their context, and how well they balance competing demands on them. Kashdan (2010) also discusses Psychological Inflexibility in that it encompasses an individual who is at the other extreme of those elements of Psychological Flexibility and is characterised by an individual who is rigid, lacks sensitivity to context, and is inflexible in their thinking. Psychological Flexibility is the core mechanism of change in Acceptance and Commitment Therapy (ACT), a modern form of Cognitive Behavioural Therapy (Hayes *et al.*, 2006). ACT proposes a model of influences on human behaviour that consists of six core processes that are overlapping and interdependent and together form Psychological Flexibility. These six processes are one side of the coin and each have a counterpart, and these counterparts together form the concept of Psychological Inflexibility (Figure 3.1) (Hayes *et al.*, 2006). Newer research has suggested that this model could be grouped in to three overarching themes representing response styles of openness, awareness and engagement (Hayes *et al.*, 2010).

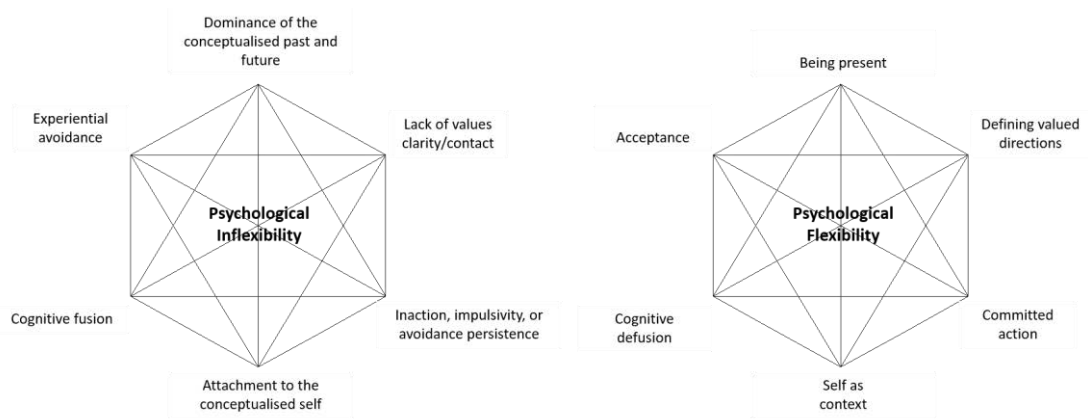


Figure 3.1 – The ACT model of Psychological Flexibility/Inflexibility, two sides of the same coin, adapted from Luoma *et al.* (2007)

Psychological Flexibility is associated with increased QoL, lower psychological distress and greater wellbeing (Kashdan & Rottenberg, 2010). This finding has been replicated in clinical health populations (McCracken & Velleman, 2010), but is less well researched in cancer populations. However, there is emerging evidence that targeting Psychological Flexibility when treating psychological distress in cancer patients might be a useful alternative to other types of psychological interventions (Hulbert-Williams *et al.*, 2016). As discussed above there is evidence that men use avoidance strategies to cope with the emotional impact of prostate cancer (Mróz, Oliffe and Davison 2013; Wall *et al.*, 2013), and avoidance is one of the six processes that contributes to Psychological Inflexibility. The literature assessing whether men with prostate cancer experience distress and poorer QoL as a consequence of their cancer is mixed, suggesting that another variable might be influencing when and how prostate cancer affects psychosocial outcomes. Given evidence that Psychological Inflexibility is associated with poorer mental health and wellbeing outcomes in general adult populations (Kashdan & Rottenberg, 2010), and researchers have suggested that it is worthy of further investigation in relation

to the psychological aspects of cancer management (Gundy *et al.*, 2011), it is important to establish the role of Psychological Inflexibility on psychosocial outcomes in men with prostate cancer. Research has also started to assess whether Psychological Flexibility might mediate or moderate relationships between predictor and outcome variables. There is a previously established link between FCR and poorer psychosocial outcomes in prostate cancer. However, the mechanisms by which FCR affect these psychosocial outcomes are less clear. Recent research has suggested that Psychological Flexibility can also influence psychosocial outcomes in cancer patients, although this is less well evidenced within men with prostate cancer. Research looking at the use of ACT has suggested that Psychological Flexibility might act as a mechanism for change and this has been found to be the case with Psychological Flexibility acting as both a mediator (Wicksell *et al.*, 2012) and a moderator (Oliver *et al.*, 2011) in previous research. Previous research has also shown that although FCR and psychosocial outcomes are correlated, they are not perfectly correlated, even when other variables such as treatment stage and treatment type (Mehta *et al.*, 2003) are taken into account. This suggests that other variables remain to be identified and added to this model. Psychological flexibility has been investigated as a mechanism of change previously, and previous reviews (Hulbert-Williams *et al.*, 2016) have suggested that greater theory building around how and when psychological flexibility affects psychosocial outcomes is required. Given a lack of previous research in this area, and that psychological flexibility has been conceptualised as both a mediator and a moderator previously, it is important to assess whether the data provides evidence for either scenario as the theory is not developed enough to be able to discount either possibility at this stage.

Aims

Despite limited research looking at the impact of Psychological Flexibility and inflexibility on cancer populations, recent papers have argued for a role of Psychological Flexibility on psychological distress in cancer patients (e.g. Hulbert-Williams *et al.*, 2016). The impact of having prostate cancer on psychosocial outcomes is also not clear, and authors have suggested that differences within the prostate cancer population around coping styles, or treatment stage might explain some of the differences in findings. Therefore, the current study aims to investigate the role of Psychological Flexibility on psychological distress and QoL in men with prostate cancer. It will also investigate the role of FCR in QoL and distress and whether Psychological Flexibility might act as a mediator or a moderator in this relationship. This is with the goal of discovering what role Psychological Flexibility plays for men with prostate cancer and potentially providing further rationale for the use of ACT in this population.

Materials and Methods

Design

This study employed a cross-sectional online survey-based design. Participants completed quantitative measures of Psychological Flexibility, FCR, psychological distress, QoL and were asked to provide relevant demographic information. Ethical approval was obtained from both the University of Edinburgh School of Health in Social Science, and from the United Kingdom National Health Service Integrated Research Assessment Service (17/LO/0620).

Participants

Participants were eligible if they currently had a diagnosis of prostate cancer or had previously been diagnosed with prostate cancer. Participant data was excluded if they indicated that either they did not have a diagnosis of prostate cancer (at which point the survey would end) or if they indicated that they received this diagnosis from a source other than an appropriate clinician.

Measures

The survey gathered data on relevant demographic information including treatment type, time since diagnosis, age, previous or current support for cancer related distress and country of residence. Standardised questionnaires measuring the following constructs were also used (see Appendix 3.B for full details of the survey).

Psychological Flexibility

Despite measures of psychological flexibility being employed in a cancer population previously (Montiel *et al.*, 2016), the above review did not identify any measures that had been specifically validated in a cancer population, nor any measures of psychological flexibility that had been adequately validated in a health population in English. Despite the AAQ-II being previously used as a measure of psychological flexibility in research using cancer patients (e.g. Montiel *et al.*, 2016), recent criticisms of this measure have identified that this scale may in fact be measuring a broader concept than psychological flexibility such as neuroticism (Rocheffort *et al.*, 2017). Therefore, this study measured psychological flexibility using the Comprehensive assessment of Acceptance and Commitment Therapy processes (CompACT: Francis *et al.*, 2016). Although this is a newer measure, it has been shown to have good internal consistency and that it has a stable three factor

structure, better aligning with the ACT model of psychopathology (Francis *et al.*, 2016).

Quality of Life (QoL)

This was measured using the Patient Orientated Prostate Utility Scale (PORPUS: Krahn *et al.*, 2000). A review of measures used to assess QoL in individuals with prostate cancer highlighted four measures that were high quality, one of which was the PORPUS (Schmidt *et al.*, 2014). The PORPUS was the only one of these four designed for use with individuals with prostate cancer at all stages of the disease (the other three being designed for use in early stage only). Test–retest reliability for the PORPUS as a psychometric instrument ranged from 0.79 to 0.81 and construct validity has been demonstrated (Ritvo *et al.*, 2005). The PORPUS is ten items. The PORPUS gives a global QoL score out of 100 with higher scores indicating greater QoL.

Psychological Distress

Psychological Distress was measured using the Depression Anxiety Stress Scales – 21 item (DASS-21: Lovibond & Lovibond, 1995; Henry & Crawford, 2005). The DASS-21 measures common symptoms of depression, anxiety and stress. It has been shown to validly measure all three aspects, whilst also providing an overall measure of psychological distress. It is known to have good internal consistency ($\alpha=.82-94$) across several samples, and concurrent validity with other measures of distress (Anthony *et al.*, 1998).

Fear of Recurrence (FCR)

This was measured by a new measure, the Fear of Cancer Recurrence Scale (FCR7: Humphries *et al.*, 2018). This seven-item scale focuses on the anxiety or fear related to FCR and provides a total score of FCR in individuals with cancer. It has

adequate internal consistency ($\alpha = 0.90$) and validity has been investigated (Humphries *et al.*, 2018). Despite the recent publication of this measure, it has been used by researchers with a range of cancer types and in a number of clinical settings previously, albeit under the name 'Fear of Recurrence Scale' (FCR7: e.g. Simard *et al.*, 2013; Rogers *et al.*, 2010). Although this measure has not been explicitly used in a prostate cancer population, measures of FCR have been used with men with prostate cancer across the treatment journey including before, during and after treatment (e.g. Mehta *et al.*, 2003).

Recruitment

Participants were men diagnosed with prostate cancer, however they did not need to currently be in an active phase of illness. Individuals were recruited through a variety of sources. Posters and business cards that advertised the study and gave information on how to take part were located in clinical areas such as general **practice surgeries, Maggie's cancer centres, churches** and cancer treatment centre waiting rooms. Cancer clinicians, including oncologists and specialist cancer nurses were provided with information to give out to potential participants that they came in to contact with. As this was a multisite study, clinicians from across Scotland were contacted regarding the survey. Sites in Glasgow, Aberdeen and Fife agreed to host the study and advertise the survey through their clinical services. Other **services (such as cancer charities and Maggie's centres) across the United Kingdom** and Ireland also agreed to assist with advertising the study, for example multiple **Maggie's centres in England**, Scotland and Wales and charities in Ireland all agreed to advertise the survey. Online recruitment was undertaken via online support networks, Facebook groups, twitter and through a website specifically designed to

advertise the study. This was with the aim of making the survey accessible to as wide a variety of individuals from as many geographical areas as possible.

Individuals recruited to the study accessed an online survey hosted by the Bristol Online Survey Tool. Individuals were prompted to give consent to the study (and any who did not give consent were taken to the last page of the survey) and were prompted to confirm that they had a diagnosis of prostate cancer. 147 individuals completed the survey, three indicated that they did not have a diagnosis of prostate cancer and their data was excluded from further analyses.

Analytic plan

Missing Data

Missing data was investigated using SPSS's missing data analysis function at the individual item level to determine if there was any pattern in missing data for a specific item. Investigation of the output revealed very little missing data (the largest item for missing data was age which had 10.40% of missing data) and no clear patterns to the missing data, which was confirmed by Little's MCAR test being non-significant, suggesting that the data was missing completely at random; $\chi^2=2115.99_{(df=2156)}$, $p=.727$. Following this, missing data was imputed using an expectation maximisation method as this has been shown to be appropriate with data that is missing at random and missing completely at random (Enders, 2011). It should be noted that the total score for the PORPUS is calculated with a formula **that allows for individual's to have missed up to two items.** Therefore, this formula was used, and as no participants missed more than two items, no data required to be imputed for this measure.

Assumptions

The data was investigated to assess whether it met assumptions required for parametric analysis. The data was ordinal, was gathered in a way that it was possible to assume independence of observations and that it met the assumption of related pairs. Histograms for each variable were investigated to confirm normal distribution. For each of the regressions, scatterplots were investigated and these confirmed that the relationships between the variables were linear and that the variability was similar for each variable suggesting that the assumptions of linearity and homoscedasticity were not violated. Multicollinearity was assessed for each analysis by investigation of tolerance and Variance Inflation Factor (VIF). This revealed, for all analyses, tolerance was above .10 and VIF was below 10 suggesting that the multicollinearity assumption had not been violated according to guidelines suggested by Pallant (2010).

Main Analyses

The data was analysed using IBM SPSS Statistics 24. Descriptive statistics, covariate analysis and correlations were undertaken. Multiple regression analysis, using a forced entry method was used to compare the strength of association between each of the predictor variables and the dependent variables simultaneously, as outlined by Gillanders *et al.* (2015). Whilst regression can compare strength of association between multiple variables simultaneously, it cannot model complex interplay between variables in arriving at outcomes. For this reason, conditional process analysis was conducted to investigate moderation and mediation effects. **Hayes'**

(2013) PROCESS tool was used to assess whether Psychological Flexibility acts as a mediator or a moderator between FCR and the outcome variables, using the **bootstrapped product of coefficient's approach**.

Sample size

Sample size was calculated a priori using the G*Power programme (Faul *et al.*, 2007). Research assessing correlations between FCR and psychosocial outcomes in men with prostate cancer have identified medium effects (e.g. Hart *et al.*, 2008). Despite a lack of research assessing correlations between Psychological Flexibility and psychosocial outcomes in men with prostate cancer, research looking at other cancer types or mixed cancer samples have identified medium to large effect sizes (e.g. Hulbert-Williams & Storey, 2016). Therefore, sample size was calculated based on the ability to detect medium sized effects and larger ($f=0.15$) and power was set at 0.80. Alpha level was set at 0.05. This research aims to establish how well seven predictors (Psychological Flexibility, FCR, treatment type, time since diagnosed, age, current or past psychological support for cancer related distress and country of residence) affect two different outcome variables (QoL and psychological distress). Therefore, for a multiple regression with seven predictors the sample size required was 103.

Hypothesis

It was hypothesised that the key predictor and outcome variables would be correlated with each other and that the predictor variables (Psychological Flexibility and FCR) would each explain statistically significant proportions of the variance in each of the outcome variables (psychological distress and QoL). Research suggests

that FCR is related to poorer psychosocial outcomes, and that Psychological Flexibility has been shown to act as a mediator and a moderator in other clinical samples. To investigate whether Psychological Flexibility acting as a moderator or a mediator best fits the data will be assessed with two hypotheses that Psychological Flexibility will act as a mediator (as in Figure 3.2) and that it will act as a moderator (as in Figure 3.3) between FCR and the outcome variables.

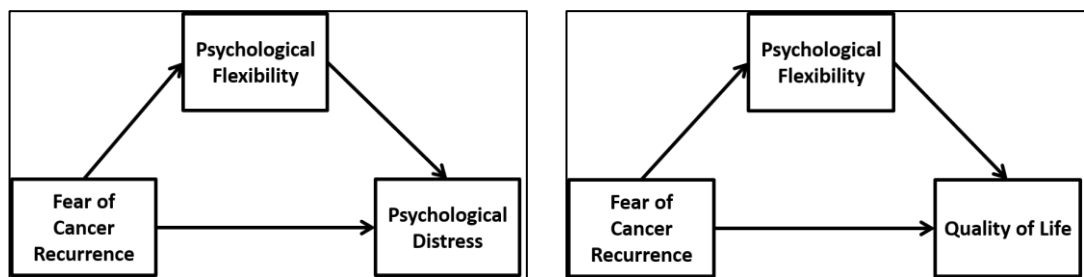


Figure 3.2 Psychological Flexibility as a mediator between fear of cancer recurrence and outcome variables psychological distress and QoL.

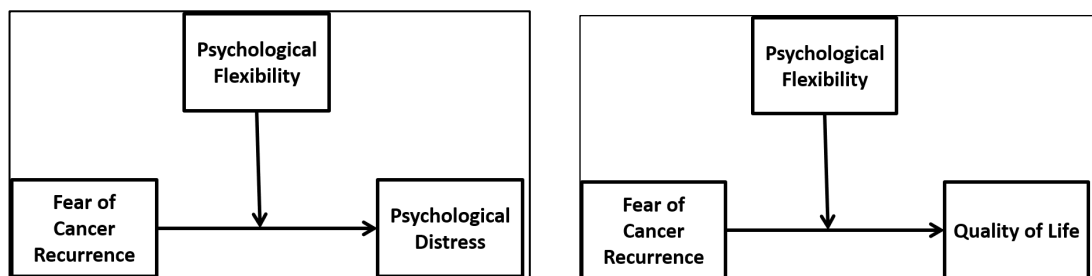


Figure 3.3 Psychological Flexibility as a moderator between fear of cancer recurrence and outcome variables psychological distress and QoL.

Results

Sample Characteristics

Sample characteristics on the demographic items can be found in Table 3.1 along with normative data. This indicates that this sample is similar to United Kingdom (UK) normative data on most of the demographic variables with the exception of treatment and country of residence. Regarding country of residence, a higher proportion of participants were resident in Scotland than might be expected given the UK normative data. This sample also held a higher proportion of individuals on active treatments (surgery and other active, non-surgery treatments). Table 3.2 demonstrates descriptive statistics for this sample of the main predictor and outcome variables compared to normative data. This revealed that the current sample is similar to normative data although contained individuals that reported slightly lower levels of FCR and higher levels of distress than has been found in other samples. However, these differences are minor.

| | Range | Mean (SD) | Normative Data Mode (%) |
|---|---------------------|------------------|--------------------------------|
| Age | 43-87 | 68.5 (7.2) | 40-69 (56.7) ¹ |
| Years since diagnosis | 1-26 | 6.0 (4.13) | 1-5 (38.0) ¹ |
| | | N (%) | Normative Data % |
| Country resident in | UK (England) | 91 (63.2) | 85.0 ¹ |
| | UK (Scotland) | 46 (31.9) | 7.0 ¹ |
| | UK (Wales) | 6 (4.2) | 5.5 ¹ |
| | Ireland | 1 (0.7) | - |
| Previous or current psychological support | No | 125 (86.8) | - |
| | Yes | 17 (11.8) | - |
| | Don't Know | 2 (1.4) | - |
| Treatment | Surgery | 63 (43.8) | 14.9 ² |
| | Active, not surgery | 76 (52.8) | 33.0* ² |
| | Non-active | 5 (3.5) | - |

*statistics available for radiotherapy and chemotherapy only; -data not available;

¹National Cancer Registration and Analysis Service website, Accessed April 2018;

²Cancer Research UK Website, Accessed April 2018

Table 3.1 descriptive statistics of covariate (demographic) variables.

| Variables | Score Range | Min | Max | Mean | SD | Normative Data | |
|---------------------|-------------|-------|--------|-------|-------|--------------------|--------------------|
| | | | | | | Mean | SD |
| Predictor Variables | | | | | | | |
| compACT | 0-138 | 31.00 | 135.00 | 68.47 | 6.79 | 95.04 ¹ | 15.78 ¹ |
| FCR7 | 5-35 | 7.00 | 34.00 | 15.88 | 6.47 | 18.65 ² | - |
| Outcome Variables | | | | | | | |
| DASS | 0-42 | 00.00 | 39.33 | 8.03 | 8.23 | 5.66 ³ | 7.74 ³ |
| OoL | 1-100 | 21.33 | 95.00 | 65.05 | 15.82 | 69.60 ⁴ | 11.70 ⁴ |

¹Gillanders *et al.* (in preparation); ²Rogers *et al.* (2010); ³Henry & Crawford (2005);

⁴Bremner *et al.* (2007).

Table 3.2 descriptive statistics of key predictor and outcome variables.

Covariate Analysis

We gathered data on variables (such as treatment type, age, years since diagnosis) that have previously been shown to impact on the outcome variables. We initially entered these variables as control variables, however these did not significantly

predict any of the variance in our outcome variables in our sample and therefore they were removed from the analysis in order to preserve power.

Correlation Analysis

Correlation analyses were conducted to assess how related the variables were with each other. This revealed that all variables were significantly correlated with each other (Table 3.3). Correlations were medium with the exception of the correlations between the compACT and the DASS and the DASS and the PORPUS which were **large (according to Cohen’s 1988 guidelines)**.

| Variable | compACT | FCR7 | DASS | PORPUS |
|----------|---------|--------|--------|--------|
| compACT | - | | | |
| FCR7 | -.40* | - | | |
| DASS | -.67** | .48** | - | |
| PORPUS | .37** | -.49** | -.53** | - |

**p<.001 (2-tailed)

Table 3.3 – correlation analysis for all variables.

Regression analysis

Regression analyses revealed that the FCR7 and the compACT as a whole explained 49% of the variance in the DASS, $AdjR^2=.49$, $F_{(2,141)}=69.67$, $p<.0001$, with the compACT making a larger contribution to the variance of the DASS than the FCR7 (Table 3.4). The FCR7 and the compACT as a whole explain 26% of the variance of the PORPUS, $AdjR^2=.26$, $F_{(2,141)}=26.53$, $p<.0001$. FCR7 was a stronger predictor of the variance in the PORPUS compared to the compACT (Table 3.4).

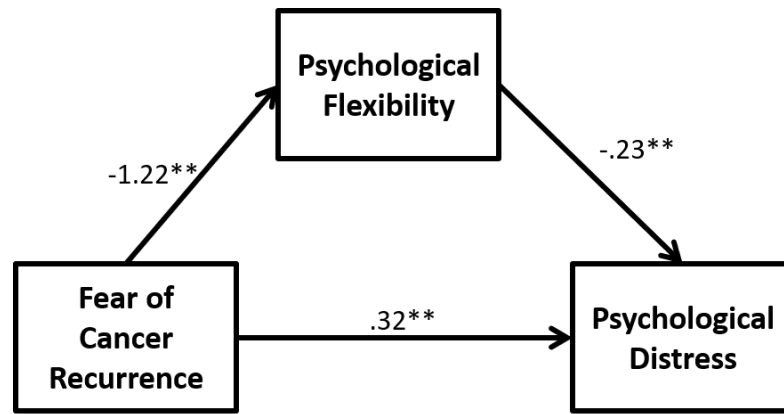
| Variables | β | t | p | R^2 | Adj R^2 | F(2,141) | p |
|-------------------------------|---------|-------|--------|-------|-----------|----------|--------|
| Dependent Variable: DASS | | | | .50 | .49 | 69.67 | <.0001 |
| compACT | -.56 | -8.66 | <.0001 | | | | |
| FCR7 | .25 | 3.90 | <.0001 | | | | |
| Dependent Variable: PORPUS | | | | .27 | .26 | 26.53 | <.0001 |
| compACT | .21 | 2.64 | <.0001 | | | | |
| FCR7 | -.41 | -5.17 | <.0001 | | | | |

Table 3.4 – Linear regression for the prediction of two dependent variables, DASS and PORPUS.

Conditional Process Analysis

Psychological Flexibility as a mediator

There was a significant indirect effect of FCR on psychological distress via Psychological Flexibility, $b=.29$, *BCa CI* [.16, .42] (Figure 3.4). The model as a whole explained 50% of the variance in psychological distress, $R^2=.50$, $F_{(2,141)}=69.67$, $p<.0001$, which is 26% more than the variance explained by FCR alone, $R^2=.23$, $F_{(1,142)}=42.35$, $p<.0001$. There was also a significant indirect effect of FCR on QoL through Psychological Flexibility, $b=-.20$, *BCa CI* [-.38, -.06] (Figure 3.5). The total model explained 27% of the variance in QoL, $R^2=.27$, $F_{(2,141)}=26.53$, $p<.0001$, whereas the total effect of FCR on QoL alone explained 24% of the variance in QoL, $R^2=.24$, $F_{(1,142)}=44.26$, $p<.0001$.



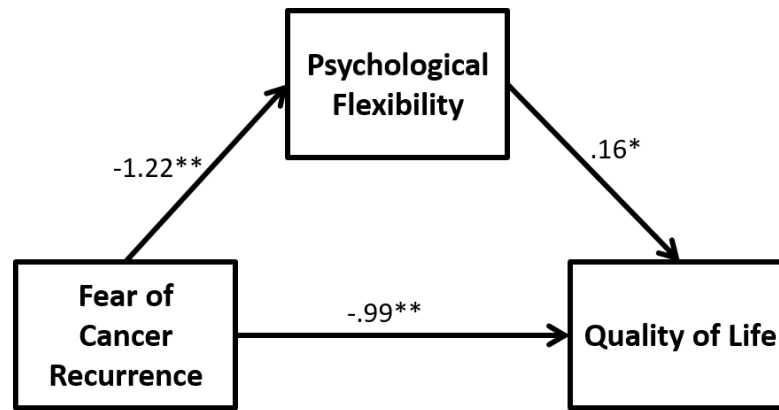
| Path | b | LLCI | ULCI |
|--------------------------------|-------|-------|------|
| Direct (FCR to Psych Distress) | .32 | .16 | .49 |
| Indirect (via Psych Flex) | .29 | .16 | .42 |
| FCR to Psych Flex | -1.22 | -1.69 | -.76 |
| Psych Flex to Psych Distress | -.23 | -.29 | -.18 |

Model Summary: $R^2 = .50$, $F_{(2,141)} = 69.67$, $p < .0001$

Total Effect Model: $R^2 = .23$, $F_{(1,142)} = 42.35$, $P < .0001$

** $p < .0001$. LLCI (Lower Level Confidence Interval), ULCI (Upper Level Confidence Interval).

Figure 3.4 – Psychological Flexibility (Psych Flex) as a mediator between Fear of Cancer Recurrence (FCR) and Psychological Distress (Psych Distress).



| Path | b | LLCI | ULCI |
|---------------------------|-------|-------|------|
| Direct (FCR to QoL) | -.99 | -1.37 | -.61 |
| Indirect (via Psych Flex) | -.20 | -.38 | -.06 |
| FCR to Psych Flex | -1.22 | -1.69 | -.76 |
| Psych Flex to QoL | .16 | .04 | .29 |

Model Summary: $R^2 = .27$, $F_{(2,141)} = 26.53$, $p < .0001$

Total Effect Model: $R^2 = .24$, $F_{(1,142)} = 44.26$, $p < .0001$

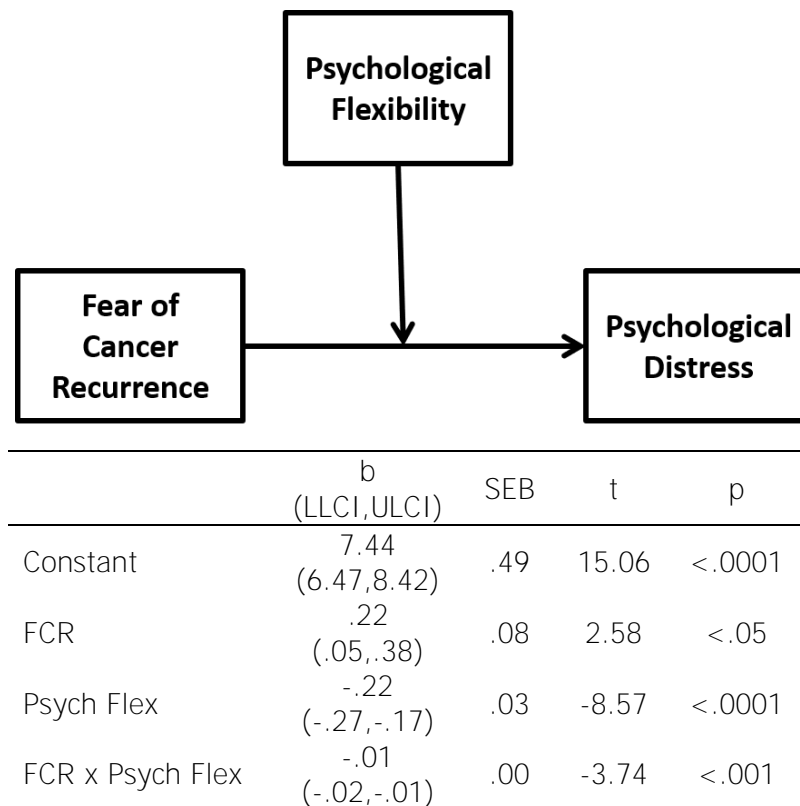
** $p < .0001$, * $p < .05$. LLCI (Lower Level Confidence Interval), ULCI (Upper Level Confidence Interval).

Figure 3.5 – Psychological Flexibility (Psych Flex) as a mediator between Fear of Cancer Recurrence (FCR) and Quality of Life (QoL).

Psychological Flexibility as a moderator

Moderation analysis revealed that Psychological Flexibility did not significantly moderate the relationship between FCR and QoL, $b = .00$, 95% CI [-.01-.02], $t = .61$, $p = .54$ (Figure 3.7). Psychological Flexibility was shown to moderate the relationship between FCR and psychological distress, $b = -.01$, 95% CI [-.02, -.01], $t = -3.74$, $p < .001$ (Figure 3.6). Further investigation of this moderating effect revealed that at low levels of Psychological Flexibility there is a significant, positive relationship between FCR and psychological distress, $b = .45$, 95% CI [.28, .62], $t = 5.24$, $p < .0001$. However, at high levels of Psychological Flexibility, this relationship

between FCR and psychological distress is no longer significant, $b = -.01$, 95% CI [- .24, .23], $t = -.07$, $p = .94$.



$R^2 = .54$, $F_{(3,140)} = 55.37$, $P < .0001$

Figure 3.6 – Psychological Flexibility (Psych Flex) as a moderator between Fear of Cancer Recurrence (FCR) and Psychological Distress.

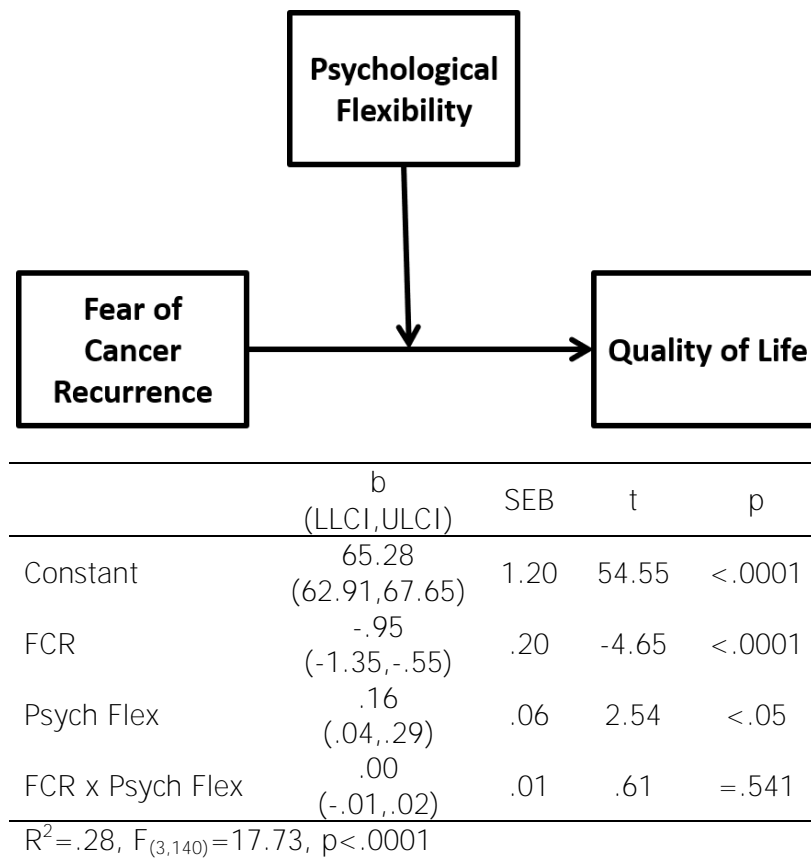


Figure 3.7 – Psychological Flexibility (Psych Flex) as a moderator between Fear of Cancer Recurrence (FCR) and Quality of Life.

Discussion

This study found that both as a whole, and individually, Psychological Flexibility and FCR significantly explained variance in both psychological distress and QoL. Psychological Flexibility was found to mediate the relationship between FCR and QoL and FCR and psychological distress. Psychological Flexibility acted as a moderator of the relationship between FCR and psychological distress.

Correlations

Simple correlations of the predictor and outcome variables demonstrated that all the concepts under investigation are correlated with each other. This highlights the interconnectedness of these concepts for men with prostate cancer. Previous research looking at these concepts has shown that they are related (Hart *et al.*, 2008; Bellizzi *et al.*, 2008; McCracken & Velleman, 2010) in individuals with cancer or other clinical populations, however, this has not been confirmed for men with prostate cancer previously.

Regression Analyses

Psychological Flexibility was shown to uniquely predict statistically significant variance in both psychological distress and QoL. Psychological Flexibility predicted more variance in psychological distress than in QoL; if scores on the measure of Psychological Flexibility were to increase by one SD, scores on the measure of psychological distress would increase by over half a SD, whereas scores on the QoL measure would increase by just under a quarter of a SD. ACT, which aims to **increase a person's ability to be psychologically flexible, does not directly aim to** change the distress that an individual is feeling, rather it aims to increase the ability of a person to be able to live a life more fully in line with their values whilst accepting unwanted thoughts, feelings and sensations (Ciarrochi *et al.*, 2010). Despite this, many studies do conclude that Psychological Flexibility increases and psychological distress decreases following ACT for cancer patients (Montiel *et al.*, 2016), and that Psychological Flexibility is negatively correlated with psychological distress in other populations (McCracken & Velleman, 2010). Previous research looking at a diverse cancer population that included some men with prostate cancer

concluded that QoL and Psychological Flexibility were significantly correlated, and that Psychological Flexibility explained some unique variance in QoL, even once the effect of demographic variables and other outcome variables were taken into account (Hulbert-Williams & Storey, 2016). However, to the authors' knowledge, no research has explicitly investigated the role of Psychological Flexibility in the levels of psychological distress and QoL experienced by men with prostate cancer.

This study also found that FCR uniquely predicts statistically significant variance in both psychological distress and QoL. However, FCR is a stronger unique predictor of the variance in QoL compared to Psychological Flexibility and predicts less of the variance in psychological distress than Psychological Flexibility. This finding is in line with previous research conducted in men who have been diagnosed with prostate cancer which demonstrated that FCR is associated with higher levels of psychological distress and lower levels of QoL (van de Wal *et al.*, 2016).

Psychological Flexibility as a Mediator

Psychological Flexibility was found to mediate the relationship between FCR and QoL and FCR and psychological distress. Previous research in other clinical areas has assessed Psychological Flexibility as a mediator (e.g. Wicksell *et al.*, 2012) and found that it can be conceptualised as this. Previous research has demonstrated that FCR is correlated with QoL and psychological distress (van de Wal *et al.*, 2016), and this research extends these findings by demonstrating that, in men with prostate cancer, Psychological Flexibility mediates these relationships. Future research might attempt to establish whether this pattern of results is applicable in other cancer diagnoses. The results in this study suggest that by targeting

Psychological Flexibility we may be able to reduce psychological distress or increase QoL. The results show that by adding Psychological Flexibility to the model, this increases the overall variance explained in psychological distress more than it increases the overall variance explained in QoL. This suggests that targeting Psychological Flexibility may have more of a direct impact on psychological distress than on QoL.

Psychological Flexibility as a Moderator

Psychological Flexibility has been shown to act as a moderator in other clinical samples (e.g. Oliver *et al.*, 2011), and this study furthered such research by demonstrating that Psychological Flexibility acts as a moderator between FCR and psychological distress. FCR only significantly predicted distress when Psychological Flexibility was at low or average levels, but not when Psychological Flexibility was high. This suggests that high levels of Psychological Flexibility may act as a protective factor against FCR resulting in less psychological distress for men with prostate cancer. This may provide further evidence for the use of therapies such as ACT in this population, as directly targeting Psychological Flexibility may protect against psychological distress associated with cancer specific constructs such as FCR. Although there is no previous literature looking at the relationship between FCR and Psychological Flexibility for men with prostate cancer, authors have suggested that, for conceptual reasons, Psychological Flexibility might be linked with FCR in cancer patients, with Psychological Flexibility acting as a protective factor against the development of high levels of FCR (Fardell *et al.*, 2016). Studies have shown that health professionals in cancer settings use elements of ACT to help patients manage levels of FCR (Thewes *et al.*, 2014). This research suggests that in

addition to these strategies that help an individual to reduce FCR, it might also be possible for an individual to be supported to behave in a more flexible way in response to their FCR in order to reduce its psychosocial impact.

Limitations

This research has several limitations. As it is cross-sectional in nature, all data was taken at a single timepoint, meaning causality is not demonstrated. Future research could look at whether interventions, such as ACT, which aim to increase Psychological Flexibility, can result in a change in psychological distress or QoL in order to begin to provide some evidence for a causal link between elements such as Psychological Flexibility and psychological distress. This study was advertised widely, using an a priori plan, however, there is potential that the way it was advertised may have biased the sample. For example, marketing was partly done through support networks and social media, and therefore individuals who are actively seeking or engaging with social support may have been more likely to have seen the advert for the study. Although this study also advertised through clinical settings, we have no data on where individuals who took part in the study saw it advertised. If this study were run again, an additional question in the survey asking where individuals heard about the survey would help in deciding whether the sample was biased towards those seeking social support. The current sample also contained a higher percentage of individuals from Scotland than would be expected given population norms for the numbers of individuals diagnosed with prostate cancer in each UK country. Although the research aimed to recruit from across the UK, the study was based in Scotland and therefore it is not unexpected that a higher proportion of participants came from Scotland. However, this may have

implications for the generalisability of the study. Due to the online nature of this survey, individuals would have required some computer literacy to take part. The survey nature and the time taken to complete it, although not overly onerous, may have resulted in individuals who were more unwell with prostate cancer not being able to take part. It was also not possible to gather data on individuals who saw the study advertised but chose not to take part. A higher proportion of individuals than would be expected compared to population norms were in active treatment, and therefore, the findings may not extend to those who are on active surveillance or watchful waiting. Future research could focus on these populations to establish whether the results are similar within a specific treatment group, such as those on active surveillance.

Future Research

Research has shown that psychosocial outcomes can impact on mortality rates in men with prostate cancer (Batty *et al.*, 2017). This research suggests that psychological flexibility is also related to psychosocial outcomes, and future research could assess whether there is any link between low levels of psychological flexibility and mortality rates in this population. Research has shown that ACT can improve outcomes for individuals with cancer (Feros *et al.*, 2011). The current research supports the rationale that the use of therapies such as ACT that aim to increase Psychological Flexibility may have an impact on the levels of psychological distress experienced by individuals with prostate cancer, their quality of life and ameliorate the impact of FCR on psychosocial outcomes. Future research could begin to extend this finding by evaluating the use of ACT in this population, in order to attempt to demonstrate a causal link between Psychological Flexibility and distress or QoL,

beyond the correlational link demonstrated in this study. Researchers have suggested that interventions that specifically target FCR need to be assessed and that existing interventions appear to be based mostly on cognitive behavioural therapy (Lebel *et al.*, 2017). The current research suggests that whilst FCR is associated with distress and QoL, Psychological Flexibility may have more value as a therapeutic target as it has the potential to act both as a mediator between FCR and negative psychosocial outcomes and as a protective factor against developing distress and poorer QoL. Future research might therefore focus on the use of ACT in cancer populations and whether this can result in the reduction of the impact of FCR, rather than attempts to directly change or control FCR. Psychological Flexibility and FCR explained less of the overall variance in QoL compared to the variance explained in psychological distress. This suggests that additional variables are influencing QoL in men with prostate cancer and future research could investigate what other variables affect QoL in this population. The current research used a prostate cancer population, and future research could replicate this study in other cancer populations to investigate whether these findings differ across different populations.

Clinical Implications

This research has implications for clinical practice. Firstly, it provides further evidence that Psychological Flexibility is related to psychosocial outcomes including distress and QoL in cancer patients and provides initial evidence specifically for men with prostate cancer. This suggests that ACT based treatments which aim to increase Psychological Flexibility may be of use in men with prostate cancer specifically, and perhaps in cancer patients more widely, who are struggling with the

psychosocial impact of cancer. Secondly, it provides evidence that Psychological Flexibility acts as both a mediator and moderator of the relationship between FCR and psychological distress and as a mediator between FCR and QoL. This provides evidence for the wide-reaching nature of the concept of Psychological Flexibility within this population and suggests useful interventions might focus on increasing levels of Psychological Flexibility in this population. As the relationship between FCR and psychological distress was significant at lower levels of Psychological Flexibility, this suggests that Psychological Flexibility can act as a protective factor in men with prostate cancer. Therefore, identification of Psychological Flexibility in men with prostate cancer early in their cancer journey might be helpful in order to target those with lower levels of Psychological Flexibility. Screening measures of Psychological Flexibility that are appropriate and valid in this population might be employed through cancer nurse specialists or at entry points to services. It might also be useful for all those who work with men with prostate cancer to have an understanding of Psychological Flexibility and its impact in order for psychosocial difficulties to be identified early. Low level interventions that aim to increase levels of Psychological Flexibility that could be delivered by healthcare professionals not trained specifically in ACT might increase the availability of these interventions. This may help to increase levels of Psychological Flexibility across the population of those with prostate cancer, without the need for a large increase in resources. It may also have the secondary impact of reducing the need for more specialised clinical services, allowing these services to dedicate more resources to complex cases.

Conclusion

This research has demonstrated that Psychological Flexibility impacts distress and QoL directly and via mediating and moderating the effect of FCR. Identifying predictors of poor psychosocial outcomes in men with prostate cancer that are targetable with existing interventions such as ACT is not only important to improve the lives of men with prostate cancer but also to potentially reduce mortality rates which have recently been shown to be linked with psychological distress (Batty *et al.*, 2017).

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DESCRIPTION

The *Journal of Contextual Behavioral Science* is the official journal of the [Association for Contextual Behavioral Science \(ACBS\)](#).

Contextual Behavioral Science is a **systematic and pragmatic approach** to the understanding of behavior, the solution of human problems, and the promotion of human growth and development. Contextual Behavioral Science uses **functional principles and theories** to analyze and modify action embedded in its historical and situational context. The goal is to **predict and influence behavior**, with precision, scope, and depth, across all behavioral domains and all levels of analysis, so as to help create a behavioral science that is more adequate to the challenge of the human condition.

Contextual behavioral science is a strategic approach to the analysis of human behavior that proposes the need for a **multi-level** (e.g. social factors, neurological factors, behavioral factors) and **multi-method** (e.g., time series analyses, cross-sectional, experimental) exploration of **contextual and manipulable** variables relevant to the prediction and influence of human behavior.

The journal considers papers relevant to a contextual behavioral approach including: Empirical studies (without topical restriction - e.g., clinical psychology, psychopathology, education, organizational psychology, etc.) Brief reports on preliminary, but provocative findings Reviews (systematic reviews and meta-analyses are preferred) and Conceptual and philosophical papers on contextual behavioral science

We are particularly interested in: Papers emphasizing the study of core **behavioral processes** that are relevant to a **broad range of human problems** Papers **bridging different approaches** (e.g., connecting behavioral approaches with cognitive views; or neurocognitive psychology; or evolutionary science) Papers that **challenge** a contextual behavioral science approach from an informed perspective

The journal welcomes papers written by researchers, practitioners, and theoreticians from different intellectual traditions. What is distinctive is not a narrowly defined theory or set of applied methods but whether the methodology, conceptualization, or strategy employed is relevant to a contextual behavioral approach.

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The Journal welcomes suggestions for Special Issues. Proposals for a themed Special Issue should be sent to the Editor-in-Chief, Emily Sandoz at emilysandoz@louisiana.edu, and should include suggested Executive, Advisory or Guest Editors, a proposed call-for-papers, 6-10 provisional authors and topics (specific titles or general areas), a proposed timeline for submission, peer-reviewing, revision and publication. All manuscripts in a special issue will be subject to the normal process of peer-review.

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GUIDE FOR AUTHORS

Types of article

All manuscripts must clearly and explicitly be of relevance to CBS. You may find the JCBS article "[Contextual Behavioral Science: creating a science more adequate to the challenge of the human condition](#)" helpful in assessing whether your manuscript is likely to be of interest to readers of this journal.

Articles should fall into one of seven categories:

1. Empirical research (up to 6000 words)
2. Brief empirical reports (up to 3000 words)
3. Review articles (up to 10,000 words)
4. Conceptual articles (up to 6000 words)
5. In practice (up to 3000 words)
6. Practical innovations (up to 3000 words)
7. Professional interest briefs (up to 3000 words)

Word limits exclude references, tables and figures but include the abstract

1. Empirical research. JCBS welcomes manuscripts across a breadth of domains from basic behavioral science to clinical trials. Research concerning the measurement and testing of process of change is particularly welcome. Potential methodologies include but are not limited to: randomized controlled trials, single case experimental designs, cross-sectional and prospective cohort studies, mixed-methods designs, small scale analog studies. Papers reporting null findings are also welcome if their methodology is sound and their power sufficient. Authors of such papers will need to emphasize the implications of their findings for future research and practice.

2. Brief empirical reports. Manuscripts in this section may report preliminary, provocative or replicated results. Empirically sound methodology and adequate power remain important considerations.

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4. Conceptual articles. Manuscripts in this section should address conceptual or theoretical issues relevant to CBS. This may include papers that discuss relevant philosophical assumptions and traditions, or conceptual papers which explore aspects of or inconsistencies in contextual behavioral theory and science.

5. In practice. Manuscripts in this section are designed to make CBS useful to practitioners from a wide variety of areas. Manuscripts must be written in an accessible style and should be easily understood by practitioners who are not experts in research or basic behavioral science. Manuscripts should provide both clear insights for new practitioners as well as stating the questions that remain to be answered by future research.

6. Practical innovations. Manuscripts in this section seek to apply the findings and applications of CBS to under-studied, under-served or novel areas. The scope of these manuscripts is limited only by the journal's broad mission: creating a science more adequate to the challenge of the human condition.

7. Professional interest briefs. Manuscripts in this section highlight professional issues of relevance to those working in the field of CBS. Examples include manuscripts related to training and supervision, assessment methods in professional settings or opinions on contemporary issues.

The Journal welcomes suggestions for Special Issues. Proposals for a themed Special Issue should be sent to the Editor-in-Chief, Emily Sandoz at emilysandoz@louisiana.edu, and should include suggested Executive, Advisory or Guest Editors, a proposed call-for-papers, 6-10 provisional authors and topics (specific titles or general areas), a proposed timeline for submission, peer-reviewing, revision and publication. All manuscripts in a special issue will be subject to the normal process of peer-review.

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Appendix 3.B – Online survey questions

Psychological Flexibility in Prostate Cancer Survey

Welcome to the survey

Thank-you for considering to take part in this survey. Please [click here](#) for a copy of the participant information sheet (Version 3, May 2017) for more information about the survey.

By taking part in the survey you are indicating you have read and agree with the following points.

- I confirm that I have read and understand the participant information sheet available above. I have had the opportunity to consider the information, and if relevant, asked questions and had these answered satisfactorily.
- I understand that my participation is voluntary and that I am free to withdraw at any time, without giving a reason and without my medical care or legal rights being affected.
- I understand that the data I provide will be anonymous. This means my data will not be identifiable to anyone. It also means that it is not able to be withdrawn should I wish it to be at a future date.
- I understand that by taking part in this survey I am giving my informed consent to taking part in the research as described in the participant information sheet (Version 3, May 2017).

Please click next to take part in the survey. By clicking next you are indicating you have understood the above points and are agreeing to take part and have your answers used to inform this research.

Demographics

What is your age?

What country do you currently live in?

- Australia
- Canada
- Ireland
- New Zealand
- United Kingdom - England
- United Kingdom - Northern Ireland
- United Kingdom - Scotland
- United Kingdom - Wales
- United States of America
- Other

If you selected Other, please specify:

Do you have a diagnosis of Prostate Cancer?

- Yes
- No

Who diagnosed you with Prostate Cancer?

- Doctor that specialises in cancer

- Other Doctor
- Nurse
- Other Health Care Professional
- Myself
- Other

If you selected Other, please specify:

When were you diagnosed with prostate cancer? *(Please give month and year if possible)*
Optional

Which of the following options would best describe what treatment(s) you have received? (you can select more than one) *Optional*

Please select at least 1 answer(s).

- Active surveillance
- Watchful waiting
- Surgery
- External beam radiotherapy
- Permanent seed brachytherapy
- Hormone therapy
- Temporary brachytherapy
- HIFU (High-intensity focused ultrasound)
- Cryotherapy
- Chemotherapy
- I don't know
- Other

If you selected Other, please specify:

The next three questions ask about any additional support you have received for distress you may have experienced due to your cancer. By additional support we mean any support you have received specifically for psychological distress you have experienced due to your cancer diagnosis.

Have you ever received any support from a psychological therapist for distress associated with your cancer diagnosis?

Yes

No

I don't know

Have you ever received support from a peer support network for distress associated with your cancer diagnosis?

Yes

No

I don't know

Have you ever received any other forms of support for distress associated with your cancer diagnosis?

Yes

No

I don't Know

If Yes - Please Specify

| | |
|--|--|
| | |
|--|--|

Questionnaire 1

Please rate the following 23 statements using the scale provided:

| | 0 - Strongly disagree | 1 - Moderately disagree | 2 - Slightly disagree | 3 - Neither agree nor disagree | 4 - Slightly agree | 5 - Moderately agree | 6 - Strongly agree |
|--|-----------------------------|-------------------------------|-----------------------------|--|--------------------------|----------------------------|--------------------------|
| 1. I can identify the things that really matter to me in life and pursue them | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. One of my big goals is to be free from painful emotions | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. I rush through meaningful activities without being really attentive to them | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. I try to stay busy to keep thoughts or feelings from coming | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. I act in ways that are consistent with how I wish to live my life | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

| | | | | | | | |
|---|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| 6. I get so caught up in my thoughts that I am unable to do the things that I most want to do | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 7. I make choices based on what is important to me, even if it is stressful | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 8. I tell myself that I shouldn't have certain thoughts | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 9. I find it difficult to stay focused on what's happening in the present | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 10. I behave in line with my personal values | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 11. I go out of my way to avoid situations that might bring difficult thoughts, feelings, or sensations | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

| | | | | | | | |
|--|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| <p>12. Even when doing the things that matter to me, I find myself doing them without paying attention</p> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <p>13. I am willing to fully experience whatever thoughts, feelings and sensations come up for me, without trying to change or defend against them</p> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <p>14. I undertake things that are meaningful to me, even when I find it hard to do so</p> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <p>15. I work hard to keep out upsetting feelings</p> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <p>16. I do jobs or tasks automatically, without being aware of what I'm doing</p> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

| | | | | | | | |
|---|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| 17. I am able to follow my long terms plans including times when progress is slow | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 18. Even when something is important to me, I'll rarely do it if there is a chance it will upset me | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 19. It seems I am "running on automatic" without much awareness of what I'm doing | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 20. Thoughts are just thoughts - they don't control what I do | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 21. My values are really reflected in my behaviour | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

| | | | | | | | |
|--|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| 22. I can take thoughts and feelings as they come, without attempting to control or avoid them | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 23. I can keep going with something when it's important to me | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Questionnaire 2

The questions on this page ask you about how you have been feeling. There are no right or wrong answers; please choose the statements that come closest to describing your experiences.

1. Pain and Disturbing Body Sensations (pain, hot flashes, painful swelling of breasts, nausea, drowsiness) Please choose the statement that comes closest to describing you **in the last two weeks**.

- No pain and no disturbing body sensations.
- Mild pain or disturbing body sensations that do not limit any activities (for example: work, social, sexual, sleep).
- Moderate pain or disturbing body sensations that limit a few activities.
- Moderate to severe pain or disturbing body sensations that limit some activities.
- Severe pain or disturbing body sensations that limit many activities

2. Energy Please choose the statement that comes closest to describing you **in the last two weeks**.

- Please select no more than 1 answer(s).
- Very full of energy, lots of pep.
 - Fairly energetic, no limitation of activities (for example: work, social, sexual).
 - Moderate reduction in energy or pep that limits a few activities.
 - Generally low energy or pep that limits some activities.
 - No energy or pep at all. I feel drained, and many activities are limited

3. Support From Family and Friends Please choose the statement that comes closest to describing you **in the last two weeks**.

Please select no more than 1 answer(s).

- Most of the time feel supported by my spouse, family and friends.
- A fair amount of the time feel supported by my spouse, family and friends.
- Occasionally feel supported by my spouse, family and friends.
- Rarely feel supported by my spouse, family, and friends.

4. Communication With Doctor (primary caregiver for prostate cancer, may be specialist or family doctor) Please choose the statement that comes closest to describing you **in the last two scheduled appointments.**

Please select no more than 1 answer(s).

- Always able to express my concerns to my Doctor and get all the information or advice I need.
- Most the time, able to express my concerns to my Doctor and get all the information or advice I need.
- Some of the time, able to express my concerns to my Doctor and get all the information or advice I need.
- Rarely able to express my concerns to my Doctor and get all the information or advice I need.

5. Emotional Well-Being Please choose the statement that comes closest to describing you **in the last two weeks.**

Please select no more than 1 answer(s).

- Generally happy and free from worry, sadness, or frustration.
- A little worry, sadness, or frustration.
- Moderate worry, sadness, or frustration.
- Quite a bit of worry, sadness, or frustration.
- Extreme worry, sadness, or frustration.

6. Urinary Frequency (need to pass urine frequently during the day or night) and Urgency (difficulty delaying urination after the urge is felt to urinate, ability to "hold it") Please choose the statement that comes closest to describing you **in the last two weeks**.

Please select no more than 1 answer(s).

- No urinary frequency or urgency.
- A little urinary frequency or urgency, does not interfere with sleep or other activities (for example: work, social); no need to plan ahead.
- Some urinary frequency or urgency that interferes with sleep or other activities; may need to plan ahead.
- Quite a bit of urinary frequency or urgency; need to be near a bathroom most of the time.
- Extreme urinary frequency or urgency; need to be near a bathroom always.

7. Leaking Urine/Poor Bladder Control Please choose the statement that comes closest to describing you **in the last two weeks**.

Please select no more than 1 answer(s).

- Never, under any circumstances leak urine or lose bladder control.
- On rare occasions, leak urine or lose bladder control, does not interfere with any activities (for example: work, social, sexual, sleep).
- Occasionally leak urine or lose bladder control, interferes with a few activities.
- A moderate amount of the time, leak urine or lose bladder control, interferes with some activities.
- Most of the time, leak urine or have poor bladder control, interferes with many activities.
- Require a clamp, catheter, or collecting bag because of leaking urine or poor bladder control.

8. Sexual Function (problems with achieving/maintaining an erection)

Please choose the statement that comes closest to describing you **in the last two weeks**.

Please select no more than 1 answer(s).

- Full erections sufficient for intercourse.
- Erections sufficient for intercourse, but some reduction in firmness.
- Erections sufficient for masturbation or foreplay only.
- Erections, but not firm enough for any sexual activity.
- No erections at all.

9. Sexual Interest/Drive Please choose the statement that comes closest to describing you **in the last two weeks**.

Please select no more than 1 answer(s).

- Normal amount of sexual drive and interest for you.
- A little decrease of sexual drive or interest for you.
- Moderate decrease of sexual drive or interest for you.
- Substantial decrease of sexual drive or interest for you.
- No sexual drive or interest.

10. Bowel Problems: Diarrhea, Rectal Discomfort (pain, burning or irritation) or Constipation Please choose the statement that comes closest to describing you **in the last two weeks**.

Please select no more than 1 answer(s).

- No diarrhea, rectal discomfort, or constipation.
- Occasionally have diarrhea, rectal discomfort, or constipation.
- Frequently have diarrhea, rectal discomfort, or constipation.
- Nearly always have diarrhea, rectal discomfort, or constipation.

Questionnaire 3

Please read each statement and circle a number 0, 1, 2 or 3 which indicates how much the statement applied to you *over the past week*. There are no right or wrong answers. Do not spend too much time on any statement.

| | 0 - Did not apply to me at all | 1- Applied to me to some degree, or some of the time | 2 - Applied to me to a considerable degree, or a good part of time | 3 - Applied to me very much, or most of the time |
|---|--------------------------------|--|--|--|
| 1. I found it hard to wind down | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. I was aware of dryness of my mouth | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. I couldn't seem to experience any positive feeling at all | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. I experienced breathing difficulty (eg, excessively rapid breathing, breathlessness in the absence of physical exertion) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. I found it difficult to work up the initiative to do things | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. I tended to over-react to situations | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 7. I experienced trembling (eg, in the hands) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 8. I felt that I was using a lot of nervous energy | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 9. I was worried about situations in which I might panic and make a fool of myself | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 10. I felt that I had nothing to look forward to | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 11. I found myself getting agitated | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

| | | | | |
|--|--------------------------|--------------------------|--------------------------|--------------------------|
| 12. I found it difficult to relax | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 13. I felt down-hearted and blue | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 14. I was intolerant of anything that kept me from getting on with what I was doing | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 15. I felt I was close to panic | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 16. I was unable to become enthusiastic about anything | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 17. I felt I wasn't worth much as a person | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 18. I felt that I was rather touchy | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 19. I was aware of the action of my heart in the absence of physical exertion (eg, sense of heart rate increase, heart missing a beat) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 20. I felt scared without any good reason | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 21. I felt that life was meaningless | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Questionnaire 4

Below you will find a list of statements. Please rate how true each statement is for you by choosing a number next to it. Use the scale provided to make your choice.

| | 1 - never true | 2 - very seldom true | 3 - seldom true | 4 - sometimes true | 5 - frequently true | 6 - almost always true | 7 - always true |
|--|--------------------------|----------------------------|--------------------------|--------------------------|---------------------------|---------------------------------|--------------------------|
| 1. My painful experiences and memories make it difficult for me to live a life that I would value. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. I'm afraid of my feelings. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. I worry about not being able to control my worries and feelings. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. My painful memories prevent me from having a fulfilling life. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. Emotions cause problems in my life. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

| | | | | | | | |
|---|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| 6. It seems like most people are handling their lives better than I am. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 7. Worries get in the way of my success. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Questionnaire 5

Please read each statement and indicate how much the statement applies to you. There are no right or wrong answers. Do not spend too much time on any statement.

| | 1 - Not at all | 2 - A little | 3 - Sometimes | 4 - A lot | 5 - All the time |
|---|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| 1. I am afraid that my cancer may recur | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. I am worried or anxious about the possibility of cancer recurrence | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. How often have you worried about the possibility of getting cancer again? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. I get waves of strong feelings about the cancer coming back | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. I think about the cancer returning when I did not mean to | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. I examine myself to see if I have physical signs of cancer | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 7. To what extent does worrying about getting cancer again spill over or intrude on your thoughts and activities? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Submit Answers

Thank-you for completing the survey - Please click finish to send your responses to the researcher.

If you would like a summary of the results once this research has been completed please enter your email address below. Alternatively check back on our website at www.sites.google.com/prod/view/psychflexibilityandcancer/ in September 2018!! If you have any queries about this survey, please don't hesitate to contact the researcher on fife-UHB.psychologyresearch@nhs.net.

If you would like a summary of the results when the research has finished, please enter an email address below.

Please enter a valid email address.

Thank-you

Thank-you for completing the survey, you may now close your browser window.

Key for selection options

1 - Please click next to take part in the survey. By clicking next you are indicating you have understood the above points and are agreeing to take part and have your answers used to inform this research.

Yes - I agree to take part in this survey and for my anonymous answers to be used in this research

No - I do not wish to take part in this survey

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Chapter 5 – Thesis Appendices

Appendix 5.A – Ethical Approval



Health Research Authority
London - Brent Research Ethics Committee

80 London Road
Skipton House
London
SE1 6LH

Telephone: 02071048129

16 May 2017

Mrs Lindsay-Jo Sevier-Guy
Trainee Clinical Psychologist
NHS Fife
Psychology Department
Stratheden Hospital
Cupar
KY15 5RR

Dear Mrs Sevier-Guy

Study title: **The Impact of Psychological Flexibility on Psychological Constructs Related to Individuals' Experiences of Prostate Cancer**
REC reference: **17/LO/0620**
IRAS project ID: **221413**

Thank you for your letter of 09 May 2017, responding to the Proportionate Review Sub-Committee's request for changes to the documentation for the above study.

The revised documentation has been reviewed and approved by the sub-committee.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact please contact hra.studyregistration@nhs.net outlining the reasons for your request.

Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

You should notify the REC once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Revised documents should be submitted to the REC electronically from IRAS. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which you can make available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA Approval (England)/ NHS permission for research is available in the Integrated Research Application System, www.hra.nhs.uk or at <http://www.rdforum.nhs.uk>.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will

be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see “Conditions of the favourable opinion” above).

Approved documents

The documents reviewed and approved by the Committee are:

| <i>Document</i> | <i>Version</i> | <i>Date</i> |
|---|----------------|-----------------|
| Copies of advertisement materials for research participants [Business Card V1 March 2017] | V1 | 10 March 2017 |
| Copies of advertisement materials for research participants [Poster V1 March 2017] | V1 | 10 March 2017 |
| Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [EL Cert] | V1 | 01 August 2016 |
| Interview schedules or topic guides for participants [Survey Questions V1 March 2017] | V1 | 23 March 2017 |
| Other [PL Confirmation] | V1 | 21 July 2016 |
| Other [University of Edinburgh - Clinical Trial Liability - 2016-17] | V1 | 25 July 2016 |
| Other [University of Edinburgh - Professional Indemnity - 2016-17] | V1 | 25 July 2016 |
| Other [REC reply (project 221413), Version1, May 2017] | V1 | 09 May 2017 |
| Participant information sheet (PIS) [PIS V2, April 2017, Tracked Changes] | V2 | 28 April 2017 |
| Participant information sheet (PIS) [PIS V2, April 2017] | V2 | 28 April 2017 |
| REC Application Form [REC_Form_24032017] | | 24 March 2017 |
| Research protocol or project proposal [IRAS Protocol V1 March 2017] | V1 | 17 March 2017 |
| Summary CV for Chief Investigator (CI) [CI CV March 2017] | V1 | 10 March 2017 |
| Summary CV for supervisor (student research) [Academic Supervisor CV Jan 2017] | V1 | 27 January 2017 |

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document “After ethical review – guidance for researchers” gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:

<http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance>

We are pleased to welcome researchers and R & D staff at our RES Committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

17/LO/0620

Please quote this number on all correspondence

With the Committee's best wishes for the success of this project.

Yours sincerely

Dr Manish Saxena
Chair

Email: nrescommittee.london-brent@nhs.net

Enclosures: *“After ethical review – guidance for researchers” [SL-AR2]*

Copy to: *Ms Charlotte Smith*

Dr Amanda Wood, NHS Fife



SCHOOL of HEALTH IN SOCIAL SCIENCE
CLINICAL AND HEALTH PSYCHOLOGY

The University of Edinburgh
Medical School
Doorway 6, Teviot Place
Edinburgh EH8 9AG

Telephone 0131 651 3969
Fax 0131 650 3891
Email submitting.ethics@ed.ac.uk

Lindsay-Jo Sevier-Guy
Trainee Clinical Psychologist
School of Health in Social Science
University of Edinburgh

09 June 2017

Dear Lindsay-Jo,

Application for Level 1 Ethical Approval

Reference: CLIN373

Project Title: The Impact of Psychological Flexibility on Psychological Constructs Related to
Individuals' Experiences of Prostate Cancer

Academic Supervisor: Nuno Ferreira

Thank you for submitting the above research project for review by the Department of Clinical and Health Psychology Ethics Research Panel. I can confirm that the submission has been independently reviewed and was approved on the 30th May 2017.

Should there be any change to the research protocol it is important that you alert us to this as this may necessitate further review.

Yours sincerely,

Kirsty Gardner
Administrative Secretary, Clinical Psychology

Appendix 5.B – Participant Information Sheet

AN INVITATION TO TAKE PART IN A SURVEY TO INVESTIGATE:

The Impact of Psychological Flexibility on Psychological Constructs Related to Individuals' Experiences of Prostate Cancer

You are being invited to take part in a research study. Before you decide to take part, we want to be sure that you understand what it would involve if you agreed. We are therefore providing you with the following information. Please read it carefully and be sure to ask any questions you have by getting in touch with the researcher. You could also discuss it with your family and friends if you wanted. You do not have to make an immediate decision. Thank-you for reading this.

What is the purpose of this study?

Prostate Cancer can have a psychological impact such as fear the cancer may recur, distress and lower quality of life. We are interested in how different people experience and cope with these impacts. In particular, whether different ways of coping are better than others. This is with the aim of identifying new and more effective treatments for helping men to cope with the impact of having prostate cancer. We are also looking at what is the best way to measure these aspects. This will help researchers to measure this construct in the future, and also help clinicians to better evaluate the services they provide for men with prostate cancer.

Why have I been invited to take part?

Any man who has ever had prostate cancer is invited to take part, so long as you can read and understand English. We are keen to get information from men with prostate cancer with a wide range of experiences. Whether you feel you are coping well regarding your prostate cancer or if you are not doing so well at the moment, we would be grateful for you to take part to understand your experiences of having prostate cancer.

Do I have to take part?

No, you do not have to take part in the study. If, following reading this information sheet, you decide not to take part, you do not need to complete the survey. Your decision will not affect the level of care you receive.

If I agree to take part can I withdraw later from the study?

You may withdraw from the study at any time, simply by closing the browser window. If you do not get to the end of the survey, your data will not be used. However, as this survey does not take any identifiable data, if you have finished the survey it will not be possible to identify your individual data to remove it from the survey. This also means it is not possible to give individual feedback.

How long will the study last?

Taking part will take around 20 minutes. This includes the time it will take to read this information sheet and complete the survey. You will also have the option to be contacted afterwards with a summary of the findings of the research. By completing the full survey, you consent to the information being used in our research.

What will I have to do if I agree to take part?

You will take part in an online survey. This will involve answering a series of questions asking you about yourself and your experiences of having prostate cancer. This will take around 15 minutes. The survey can be found by [clicking here](#).

What are the possible benefits of taking part?

You are not expected to gain any direct benefits from completing the survey. However, taking part will help improve our understanding of the role of psychological factors in men's experience of having prostate cancer and improve the interventions offered to men with prostate cancer.

What are the possible burdens of taking part?

The main burden is the time it will take to complete the survey.

Are there any possible risks of taking part?

We do not consider there are any risks in taking part but, should you find any of the questions uncomfortable you are free to miss that question out or withdraw at any time. We do not expect that the survey will cause distress. However, if you feel distressed or physically unwell, please contact your relevant health practitioner. For further support, you could contact your local cancer charity, for example Maggie's in the UK. If you would like information regarding psychological distress you could check out www.moodcafe.co.uk.

What happens to the data that is collected?

Once enough people have taken part in the survey, the researcher will combine everyone's data together. The researchers will use statistical methods to see if there are relationships between any of the things we are measuring. This will help us to better understand why there are differences in the way that men cope with prostate cancer. This study is part of an educational project. Therefore, the findings will be written up for an academic dissertation and hopefully published in scientific journals.

Is the data confidential?

No identifiable information will be taken, and therefore you can maintain anonymity if you choose to take part. It is possible to provide an email address to get information about the findings of the study, but this is optional. Email addresses will only be available to the lead researcher. Data will be held securely, in line with University of Edinburgh's policies, within the online host site. Data will be downloaded in order for analyses to be conducted. This data will be held on a secure server accessible only to those involved in the research. Anonymised data will be held securely for at least ten years, after which it will be destroyed.

Who has reviewed the study?

The Proportionate Review Sub-Committee of the London - Brent Research Ethics Committee has examined the proposal and has raised no objections from the point of view of ethics. The University of Edinburgh has also evaluated the methodology and given ethical approval.

What should I do now if I want to take part?

If you would like to take part in the study, please complete the survey that can be found at the following web address: <https://edinburgh.onlinesurveys.ac.uk/psychological-flexibility-in-prostate-cancer-survey>

If you have any further questions about the study please contact the researcher, Lindsay-Jo Sevier-Guy on fife-UHB.psychologyresearch@nhs.net. Alternatively, you can look at the study website at www.sites.google.com/prod/view/psychflexibilityandcancer/home.

If you would like to discuss this study with someone independent of the study team please contact: Tara Graham, Research and Development Psychologist: 01334 696336/NHS Fife Department of Clinical Psychology, Stratheden Hospital, Cupar, Fife, KY15 5RR

If you wish to make a complaint about the study please contact NHS Fife, Patient Relations Department, Fife NHS Board, Room 104, Hayfield House, Hayfield Road, Kirkcaldy, KY2 5AH; patientrelations.fife@nhs.net OR Professor Charlotte Clarke, Head of the School of Health in Social Science via <http://www.ed.ac.uk/files/imports/fileManager/WEB%20Complaint%20Form.pdf>.

- THANK YOU FOR READING THIS -

Appendix 5.C – Thesis Proposal



Doctorate in Clinical Psychology

Thesis Research Proposal (For Methodological Review Only)

This form is for methodological review of projects that are **not** being submitted as assessed work for Research 1. (e.g. where a trainee has already received a pass mark for Research 1, but subsequently changed the intended thesis project, or for trainees who started training in 2009 or earlier and thus did not need to complete Research 1 and have not previously had university approval for their study).

In such circumstances the form will be reviewed by a member of the academic team and will receive detailed feedback, but will not be graded. The feedback will include an evaluation of the viability of the project and any recommendations. If there are significant concerns about viability, the project will be flagged to the research director and the research committee will decide whether the project can proceed in its current form.

Trainee Name

Lindsay-Jo Sevier-Guy

Provisional Thesis Title

The Impact of Psychological Flexibility on Psychological Constructs Related to Individuals' Experiences of Prostate Cancer

Proposed Setting

Online

Allocated Thesis Project Supervisors

| | |
|------------------------|---|
| <i>Clinical</i> | Dr Caroline Somerville |
| <i>Academic 1</i> | Dr Nuno Ferreira |
| <i>Academic 2</i> | |
| <i>Others Involved</i> | Health Psychology Team, NHS Fife; Urology Team, NHS Fife; Prostate Cancer Charities |

Anticipated Month / Year of Submission

Must be May of final year. Trainees from 2011 intake onwards must submit in May. Trainees who started in 2010 or earlier are advised to submit in May to reduce potential for HCPC registration difficulties.

May 2018

Date Form Submitted / Version

21/11/2016 Version 1

Please Note: Whilst this is not an ethics review process, where questions have some similarities to questions contained in the NHS IRAS Research Ethics form, the corresponding IRAS question numbers are given in parentheses. This is intended to facilitate completion of NHS ethics where such approval is needed.

Section 1: Introduction

1.1 Provide a brief critical review of relevant literature, which should clearly demonstrate the rationale and scientific justification for the research

1000 – 1500 words

Relevant to IRAS A12

Prostate Cancer and Psychosocial Outcomes

National Institute for Health and Care Excellence (NICE) guidelines (2014) indicate that for men, prostate cancer is the most common form of cancer, accounting for 26% of all cancer diagnosed in men. Over three quarters of men diagnosed with prostate cancer are over 65 (NICE, 2014).

Psychological Distress

Psychological Distress is defined differently throughout the cancer literature, however, the National Comprehensive Cancer Network (NCCN, 2013) definition is used most frequently:

“Distress is a multifactorial unpleasant emotional experience of a psychological (cognitive, behavioural, emotional), social, and/or spiritual nature that may interfere with the ability to cope effectively with cancer, its physical symptoms and its treatment. Distress extends along a continuum, ranging from common normal feelings of vulnerability, sadness, and fears to problems that can become disabling, such as depression, anxiety, panic, social isolation, and existential and spiritual crisis”

(pg7)

Research shows that men with prostate cancer experience psychological distress (Balderson & Towell, 2003). There are many stages in the cancer journey where psychological distress can be experienced for men with prostate cancer (e.g. diagnosis, decision making, treatment, recovery, survivorship) and research has shown that levels of distress experienced can fluctuate across these stages (Roth *et al.*, 1998). This is proposed to be due to psychological demands on these individuals differing at each stage (Hsiao *et al.*, 2011). Some studies indicate that psychological distress is lower in prostate cancer when compared to other cancers (Venderbos *et al.*, 2015), perhaps due to currently there being a higher survival rate for this form of cancer (Cancer Research UK Website, accessed 14/11/16). However, reviews looking at this have demonstrated mixed findings (Sharpley *et al.*, 2008). The diversity of the findings might be explained by the way men display distress when they have prostate cancer. Mróz, Oliffe and Davison (2013) found that men

with prostate cancer can cope with this by using emotionally detached responses such as stoicism. Wall *et al.*, (2013) conducted a qualitative study of men's experiences of the first year post their diagnosis of prostate cancer. The authors found that following a period of overt distress following the diagnosis, men used avoidance strategies to cope with further distress such as playing down the role of the psychological impact of having a diagnosis of prostate cancer. Blank & Bellizzi (2006) showed that the mixed results when looking at the levels of psychological distress in men who have survived prostate cancer may be due to the different coping styles used, with escapist coping style being negatively correlated with happiness and positive affect. Therefore, it may be that research is underestimating the level of distress associated with prostate cancer due to men using strategies to avoid their distress.

Quality of Life

Similarly, the findings related to Quality of Life (QoL) in individuals with prostate cancer seems to be mixed, fluctuating depending on their stage of cancer journey (Jeldres *et al.*, 2015; Drummond *et al.*, 2015). Katz (2007) found that men with PC's QoL is affected, regardless of what type of active treatment they are on. Specifically, it was found that the effect of the PC treatment on a man's sexual functioning had the most significant impact on their QoL (Katz, 2007). When looking across the whole cancer journey however, results are more mixed with certain stages of the prostate cancer journey being associated with lower QoL than others, for example, those who have undergone surgery tending to report lower QoL compared to those that are undergoing active surveillance (Jeldres *et al.*, 2015). QoL is a broad concept, that often includes aspects related to physical health. Active treatment for PC is known to have large impact on physical health, for example, resulting in incontinence or sexual difficulties. Therefore, studies looking at QoL in individuals on active surveillance compared to active treatment are likely to conclude that overall QoL is higher in individuals on active surveillance (e.g. Jeldres *et al.*, 2015), but this could be the physical impact of active treatment masking any psychological distress within the active surveillance population.

Fear of Recurrence

Individuals who have previously been diagnosed with prostate cancer can suffer fear that this cancer will return, and individuals currently diagnosed with prostate cancer experience similar fears that the cancer will return at some point in the future (Mehta *et al.*, 2003). Fear of recurrence can be a burden to individuals with prostate cancer before and after treatment (Mehta *et al.*, 2003). High fear of recurrence has also been shown to be related to both poorer QoL and higher psychological distress (Hart *et al.*, 2008; Bellizzi *et al.*, 2008). As with QoL and psychological distress in prostate cancer, the level of fear of recurrence can differ depending on which treatment that individuals is undergoing (Mehta *et al.*, 2003).

Acceptance and Commitment Therapy

Acceptance and Commitment Therapy (ACT) suggests that psychological suffering is part of the human condition and attempts to control this can result in further suffering (Hayes, 2004). This may be done through experiential avoidance. Experiential avoidance describes attempts made to evade private internal events (thoughts, feelings etc.), even when doing so results in a life that is not in line with our values (Hayes *et al.*, 1996). Trying to control internal events can result in a decrease in the number of behaviours willing to be carried out in case they bring up or result in the exact thoughts, feelings etc. that are being avoided (Hayes *et al.*, 2006). ACT firstly aims to help increase an individual's ability to stay with the distress that often accompanies living a life fully connected with values. One of the ways ACT does this is by providing techniques to help people overcome this experiential avoidance. Secondly, it helps individuals to re-focus on what is important to them in their lives and how they can make changes to live a life that is in line with these things.

Veehof *et al.*, (2016) conducted a meta-analysis of RCTs of ACT for mental health of chronic pain patients and concluded that ACT is significantly better than other mindfulness based approaches. They also found that ACT was not significantly poorer than CBT, concluding ACT is a suitable alternative for CBT in a chronic pain population. A review by Hulbert-Williams and colleagues (2015) concluded that there is limited evidence to date in the use of ACT with cancer populations but there is sufficient to show that positive outcomes in relation to psychological distress are possible in cancer populations. Gundy *et al.*, (2011) also concluded that ACT is worthy of further investigation in relation to the psychological aspects of cancer management. This highlights the importance of conducting research investigating the role of proposed mechanisms of action in ACT on mental health and wellbeing outcomes for individuals with prostate cancer. One of these proposed mechanisms of action is changes in psychological flexibility.

Psychological Flexibility

Psychological flexibility is an important part of psychological health and is defined by Kashdan (2010) as how well a person copes and adapts to varying psychological demands, applies mental resources flexibly, shifts their perspective depending on their context, and how well they balance competing demands on them. Kashdan (2010) also discusses psychological inflexibility in that it encompasses an individual who is at the other extreme of those elements of psychological flexibility and is characterised by an individual who is rigid, lacks sensitivity to context, and is inflexibility in their thinking. ACT proposed a model of psychopathology that consists of six core processes that are all interlinked. It is proposed that individually

these six processes are related to psychological wellbeing and together are parts of the overall construct of “psychological inflexibility” (figure 1). These six processes are said to be one side of the coin, each having their own counterpart. These six counterparts are again interlinked with each other and feed in to an overall construct of “psychological flexibility” (figure 1) (Luoma *et al.*, 2007). ACT theorises that individuals who are more psychologically flexible are better able to make values consistent behaviours in their own lives.

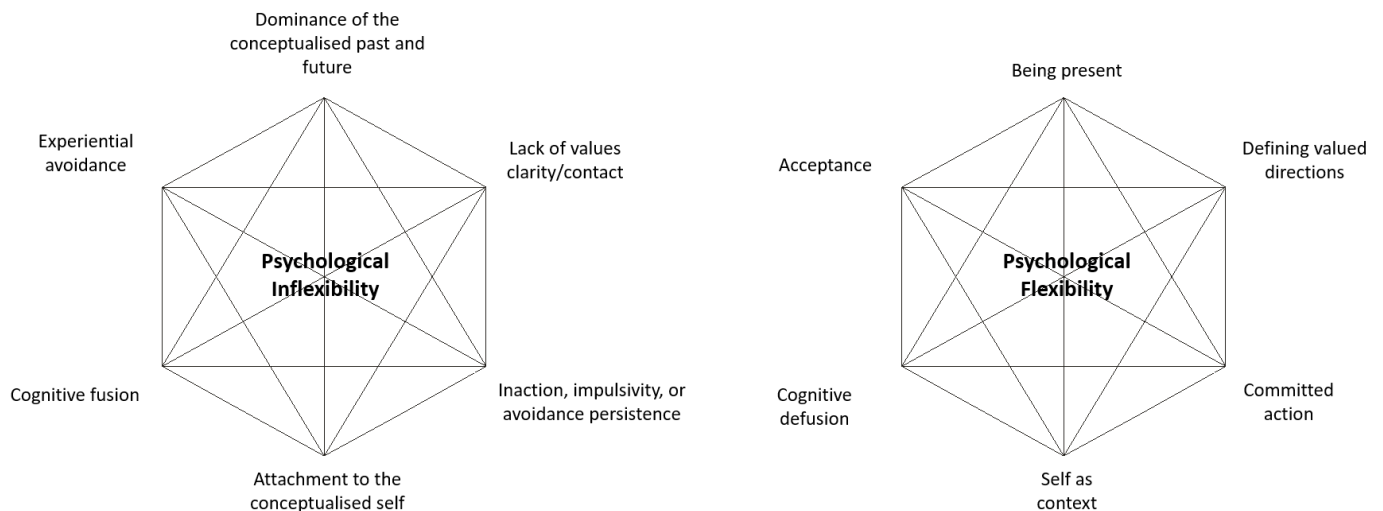


Figure 1 – The ACT model of psychopathology, two sides of the coin, adapted from Luoma *et al.*, (2007)

Research shows that psychological flexibility is associated with increased QoL, lower psychological distress and greater wellbeing (Kashdan & Rottenberg, 2010). This finding has been replicated in clinical health populations (McCracken & Velleman, 2010). This association between psychological flexibility and psychological wellbeing is less well researched in cancer populations. Despite this, there is emerging evidence that targeting psychological flexibility when treating psychological distress in cancer patients might be more effective than other types of psychological interventions (Hulbert-Williams *et al.*, 2016). As discussed above there is evidence that men use avoidance strategies to cope with the emotional impact of prostate cancer (Mróz, Oliffe and Davison 2013; Wall *et al.*, 2013). This may result due to men with prostate cancer being psychologically inflexible. Given evidence that psychological inflexibility is associated with poorer mental health and wellbeing outcomes in general adult populations (Kashdan & Rottenberg, 2010), it is important to establish the role (if any) of psychological inflexibility on mental health outcomes in men with prostate cancer.

The measurement of psychological flexibility has often relied on the use of the Acceptance and Action Questionnaire (AAQ-II; Bond *et al.*, 2011). Some authors have argued that the AAQ-II does not measure all

facets of psychological flexibility, instead only measuring some of the six processes that make up the ACT model of psychopathology (figure 1) (Wolgast, 2014). There has also been some criticism of the AAQ-II that what it measures (ACT processes) overlaps with distress outcome variables (Wolgast, 2014). A new measure of psychological flexibility has recently been developed. The compACT (Francis, Dawson & Golijani-Moghaddam, 2016) is a 23-item measure which aims to measure psychological inflexibility. It is proposed that those that score highly on this measure are high in psychological inflexibility, and those that score low on this measure are high in psychological flexibility. The compACT has not been used to measure psychological flexibility in a cancer population previously.

Rationale for Research

As discussed above there is evidence that men with prostate cancer may use elements of the construct of psychological inflexibility in order to cope with the psychological distress of having prostate cancer, namely avoidance (Mróz, Oliffe and Davison 2013; Wall *et al.*, 2013). There is evidence in the wider general adult population and clinical health populations that psychological inflexibility is associated with poorer mental health and wellbeing outcomes (e.g. Kashdan & Rottenberg, 2010; McCracken & Velleman, 2010). Despite limited research looking at the impact of psychological flexibility and inflexibility on cancer populations, recent papers have argued for a role of psychological flexibility on psychological distress in cancer patients (e.g. Hulbert-Williams *et al.*, 2016). Therefore, this research aims to investigate further the role of psychological flexibility on psychological distress, quality of life and fear of recurrence in men with prostate cancer. This is with the goal of discovering whether psychological flexibility has a role in predicting psychological distress in cancer patients and therefore providing further evidence for the use of ACT in this population. This research further aims to identify whether the compACT is a useful tool for measuring psychological flexibility in a cancer population. This is with the goal of providing researchers with evidence for using this as a tool for researching intervention studies in the future, and will also help service providers evaluate the service they offer individuals with prostate cancer.

Section 2: Research Questions / Objectives

2.1 What is the principal research question / objective?

IRAS A10

How well does psychological flexibility predict fear of cancer recurrence, QoL and Psychological Distress in individuals with prostate cancer once treatment type, age, length of time diagnosed, current or past psychological support for cancer related distress and country resident in are controlled for?

2.2 What are the secondary research questions / objectives, if applicable?

Keep these focused and concise, with a maximum of 5 research questions

IRAS A11

Is the compACT a valid and reliable tool for assessing psychological flexibility in individuals with prostate cancer?

Section 3: Methodology

3.1 Give a full summary of your design and methodology

It should be clear exactly what will happen at each stage of the project

IRAS A13

Participants

Participants will be men who have ever been diagnosed with prostate cancer. These individuals do not need to currently be in an active phase of their illness.

Design

This study aims to use a cross-sectional design to evaluate the association between psychological flexibility (as measured by the compACT), QoL (as measured by the PORPUS), psychological distress (as measured by the DASS) and fear of recurrence (as measured by the FRRS). Please see below for more details on the questionnaires proposed.

Online Survey

The data will be collected via an online survey. (Paper copies of the proposed measures will be made available to a small subset of participants if they so wish, please see protocol for more details). This survey will be hosted by the Bristol Online Survey Tool. This host has been chosen as it is supported by the University of Edinburgh and provides security features necessary to manage confidential data. The first page of this survey will be a title page that will contain information to assist the individual in providing informed consent, such as how their information will be used, what their participation involves and what to do if they no longer wish to continue with the survey. Individuals will be asked to tick a box to say that they agree to take part in the survey. If they click agree they will be taken to the rest of the survey which will contain the proposed questionnaires. If they click disagree they will be taken to the end of the survey, thanking them for their participation.

Ethical Considerations

Anonymous Data

As the survey is completed online, it will be anonymous. Therefore, it will not be possible to retrieve an individual's data if they wish for it to be withdrawn at a later stage. This will be explained to individuals in the participant information sheet as part of gaining informed consent.

Patient's becoming distressed during survey

There is a possibility that individuals may become distressed during the survey. Despite none of the questionnaires asking specifically distressing information, there is a possibility that in answering questions about their cancer the individuals may become distressed. This will be discussed in the participant information sheet and individuals will have been made aware that they are entitled to drop out of the survey at any point by closing the browser window. Information will also be provided in the participant information sheet regarding what an individual should do if they find themselves becoming distressed including details for online support charities they can contact. These contacts will also be included in a final page of the survey, reminding individuals again who they can contact if they have become distressed during the survey.

Individual's taking part in the survey to get support

It is possible that individuals who are currently struggling (for example with anxiety and depression) may take part in the survey to access support for this. The measures proposed are not diagnostic tools and this will be made clear in the participant information sheet. It will also be made clear that no feedback will be available to individuals about their specific scores. Information about charities that offer support to individuals with prostate cancer will be provided.

Protocol

Individuals who have been diagnosed with prostate cancer will be invited to take part in a survey. These individuals will be identified through the local Urology team in NHS Fife, through heads of Health Psychology in other boards and online via prostate cancer charities. Charities that have provisionally agreed to be involved in this study include; "Tackle Prostate Cancer" (UK based), "Men's Cancer Alliance" (based in Ireland), "Prostate Cancer Foundation BC" (based in Canada), and Prostate Cancer Foundation of Australia. Individuals based in NHS Fife, will be contacted through the local prostate cancer nurse who will disseminate details of the study. This will include a participant information sheet with information about the study and contact details for the researcher to ask any questions they may have. Interested individuals will be provided with a link to the online survey. Individuals recruited from NHS Fife will also be able to complete paper copies of the questionnaire if they so wish, provided to them directly by the researcher. Individuals recruited from prostate cancer charities will be contacted by these charities either through established mailing lists or by placing a link to the survey on their websites. Details of the online survey will also be disseminated through other Clinical Health Psychology teams via the heads of these teams. The information contained in the participant information sheet will also be made available to these individuals either through the email or online. Individuals will again be provided with the researcher's contact details

and encouraged to take time to think about the survey and ask any questions they may have before taking part. Individuals who would like to take part will be directed to the online survey.

Storage of Data

All individuals taking part in the study will be anonymous and it will not be possible for the researcher to identify which data has come from which individual. Any hard copies of all questionnaires will be kept in locked cabinets within the locked psychology department on NHS premises. The anonymised data gathered through Bristol Online Survey tool along with that gathered through the NHS will be held by the University of Edinburgh. This data will be kept for a minimum of ten years before being deleted. Data will be downloaded into an Excel database and stored in a limited access folder on the networked area of the NHS Fife server which is backed up daily. No identifiable data will be kept on. Following completion of the research, all electronic data will be deleted.

3.2 List the principal inclusion and exclusion criteria

IRAS A17-1 and IRAS A17-2

Inclusion:

Men who have been diagnosed with prostate cancer at any point in their life

Exclusion:

Individuals with any other type of cancer

3.3 How will data be collected?

If quantitative, list proposed measures and justify the use of these measures. If qualitative, explain how data will be collected, giving reasonable detail (don't just say "by interviews".)

Data will be collected via an online survey. This survey will contain generic questions to gather relevant demographic information including what treatment they are undertaking, how long since they were first diagnosed with prostate cancer, their age, whether they have previously or are currently receiving any formal support for their cancer related distress and what country they are resident in. Questionnaires measuring the following constructs will also be used:

Psychological Flexibility

This will be measured with the compACT (Francis, Dawson & Golijani-Moghaddam, 2016). This is a newly developed measure, which has demonstrated that it has a stable three factor structure (mapping onto the ACT model of psychopathology) and good internal consistency (Francis, Dawson & Golijani-Moghaddam, 2016).

The AAQ-II (Acceptance and Action Questionnaire-2nd version) (Bond *et al.*, 2011) will also be used to measure psychological flexibility in order to assess how the compACT relates to this older, more validated measure of psychological flexibility. The AAQ-II has demonstrated good reliability with a mean alpha coefficient of .84 and adequate discriminant validity (Bond *et al.*, 2011). This has also been used previously

as a measure of psychological flexibility in clinical populations (Kortte, 2009).

QoL

This will be measured using the PORPUS (Patient Orientated Prostate Utility Scale) (Krahn et al, 2000). A review of measures used to assess QoL in individuals with prostate cancer highlighted four measures that were high quality, one of which was the PORPUS (Schmidt *et al.*, 2014). The PORPUS was the only one of these four designed for use by individuals with prostate cancer at all stages of the disease (the other three being designed for use in early stage only). Test–retest reliability for the PORPUS as a psychometric instrument ranged from 0.79 to 0.81 and construct validity has been demonstrated (Ritvo *et al.*, 2005). The PORPUS is free to use and is reasonably short at ten items long.

Psychological Distress

Psychological Distress will be measured using the DASS-21 (Depression Anxiety Stress Scales – 21 item) (Lovibond & Lovibond, 1995). This measures depression, anxiety and tension or stress. The original DASS was 42 items, however a short form version containing 21 items has also been developed and demonstrated to have good internal consistency (.94 for the depression subscale, .87 for the anxiety subscale and .91 for the stress subscale) and concurrent validity with other measures of distress (Anthony *et al.*, 1998). The DASS-21 has been shown to validly measure all three aspects, whilst also providing an overall measure of psychological distress (Henry & Crawford, 2005). This more recent study also demonstrated the reliability of the overall scale to be .93 with the reliability for each of the subscales being .88 for depression, .82 for anxiety, and .90 for stress (Henry & Crawford, 2005).

Fear of Recurrence

This will be measured by a new scale Fear of Recurrence Scale (FoRS) developed by Ozakinci *et al.*, (in preparation; as cited in Simard *et al.*, 2013). The FoRS was used in a study by Rogers *et al.*, (2010) which demonstrates the reliability for this scale using Cronbach’s alpha as 0.90 (Rogers *et al.*, 2010).

Section 4: Sample Size

4.1 What sample size is needed for the research and how did you determine this?

For quantitative projects, outline the relevant Power calculations and the rationale for assuming given effect sizes. For qualitative projects, outline your reasoning for assuming that this sample size will be sufficient to address the study’s aims

IRAS A59 and IRAS A60

Sample size was calculated using the G*Power programme. Due to the lack of research in this area, effect size was estimated to be medium ($f=0.15$) and power was set at 0.80. Alpha level was set at 0.05. This research will establish how well six predictors (psychological flexibility, treatment type, time since diagnosed, age, current or past psychological support for cancer related distress and country resident in) affect three different outcome variables (quality of life, psychological distress and fear of recurrence). Therefore, for a multiple regression with six predictors the total sample size required will be 98.

4.2 Outline reasons for your confidence in being able to achieve a sample of at least this size

Give details of size of known available sample(s), percentage of this type of sample that typically participate in such studies, opinions of relevant individuals working in that area

As this is an online survey, individuals can be recruited from any English-speaking country. In one year in the UK as many as 34,335 individuals were diagnosed with prostate cancer (NICE, 2014). Therefore, there is a large pool of individuals to draw from. To access these individuals, the researcher will recruit from relevant cancer charities and preliminary interest from five cancer charities around the world regarding sending the survey to their members or putting a link to their survey on their website has already been garnered. Participants will also be recruited from NHS Fife directly where an active prostate cancer support group which have been amenable to taking part in research in the past is located. The local Urology Team are confident that a large proportion of the recruitment can take place within NHS Fife, for example, previously a piece of research conducted with a subset of individuals with prostate cancer in NHS Fife succeeded in recruiting over fifty individuals to this study. On discussion with academic supervisor, similar online survey research conducted in other clinical health populations have succeeded in recruiting sufficient individuals using relevant charities to disseminate information about the survey.

Section 5: Analysis

5.1 Describe the methods of analysis (statistical or other appropriate methods, e.g. for qualitative methods) by which the data will be evaluated to meet the study objectives

IRAS A62

The data will be analysed using SPSS. Relationships between each of the constructs will be analysed via correlation. Hierarchical multiple regression will be used to assess how much variance (how strong of a predictor) psychological flexibility accounts for in the outcomes of QoL, Psychological Distress or Fear of Recurrence when controlling for key demographic variables.

Section 6: Project Management / Timetable

6.1 Outline a timetable for completion of key stages of the project

E.g. ethics submission, start and end of data collection, data analysis, completion of systematic review

- Proposal agreed/not agreed and changes made **Nov – Dec 16**
- Submit ethics form **Dec 16**

- Ethics complete **Jan/Feb 17**
- Survey preparation **Dec 16 – Jan 16**
- Survey piloted with non-cancer population **Feb 17**
- Survey live **Mar 17 – Sept 17**
- Write Up:
 - Intro **Feb 17 – Jun 17** (1st draft May 17)
 - Methods **May 17 – Aug 17** (1st draft Jul 17)
 - Results **Oct 17 – Dec 17** (1st draft Nov 17)
 - Discussion **Jan 18 – Feb 18**
 - First Full Draft **Mar 18**
 - Second Full Draft **Apr 18**
 - Submit **May 18**
- Systematic Review **Mar 17 – Sept 17**

Section 7: Management of Risks to Project

7.1 Summarise the main potential risks to your study, the perceived likelihood of occurrence of these risks and any steps you will or have taken to reduce these risks. Outline how you will respond to identified risks if they should occur

Sufficient numbers not recruited from NHS Fife

As discussed, despite the opinion of the Urology Oncology team that it will be possible to recruit a large proportion of the numbers required from NHS Fife directly there is a risk that sufficient numbers will not be recruited. To ameliorate this risk, it is proposed that recruitment will be opened out to the whole of the UK and other English speaking countries. This will provide a very large pool of individuals from which to collect data from.

Life Events

It is likely that life events will occur throughout the research period that may impact on the research. The timescale proposed provides a generous amount of time for each aspect of the research, allowing some “wiggle room” for minor life events. The burden of written work has also been spread out, meaning that the pressure from these will be spread over the years the research is proposed to take place over.

Time

As this is a project that has changed from the original research proposed, there is now have less time than

previously planned. However, this is a simpler project than the original idea that is achievable despite the reduced timescale now available.

Participants becoming distressed whilst completing the survey

Please see “ethical considerations” in the methodology section, where this risk has been previously addressed.

Section 8: Knowledge Exchange

8.1 How do you intend to report and disseminate the results of the study?

IRAS A51

Initially, an open evening will be arranged where the results from this study will be presented and questions or comments discussed. Interested parties will be invited to this including NHS staff, patients and third sector organisations.

The NHS Fife Psychology Department hold a conference every two years, and the results from this study will be presented at this conference. The results will be fed back to the Health Psychology team and wider teams where possible and as appropriate.

This study aims to be published in the Journal of Contextual Behavioural Science. The results will also be made available to members of the Association for Contextual and Behavioural Science by publishing them on their website.

Finally, submissions to any relevant conferences that become available will be applied for following completion of the project.

8.2 What are the anticipated benefits or implications of the project?

E.g. If this is an NHS project, in what way(s) is the project intended to benefit the NHS?

Current measures of psychological flexibility have been criticised, with new measures now developed to try to address these criticisms. This research will further evaluate the usefulness of these measures which will help to provide more accurate measures of psychological flexibility to assess ACT interventions in the future.

This research will also evaluate how psychological flexibility links to other constructs relevant to individuals with prostate cancer. This may help inform future treatments for psychological distress in individuals with prostate cancer. There is a current need, identified by the Urology Oncology team regarding this population of patients. It is reported that psychological distress of individuals with prostate cancer is

impacting on their service with regards to extra phone calls, examinations and appointments for these individuals. Therefore, if more targeted interventions can be provided for this population, this may improve the service for individuals with prostate cancer and ultimately save the service money.

8.3 Are there any potential costs for the project?

Outline any potential financial costs to the project, including the justification for the costs (why are these necessary for the research project?) and how funding will be obtained for these costs (how will they be met?) Please separate these into potential costs for the University and potential costs for your NHS Board and note that you should ask your NHS Board to meet stationery, printing, postage and travel costs.

NHS Board

The NHS board will cover costs for printing, stationery and postage required for gathering data. I plan to attend ACT training and will request CPD time, but will fund the training myself.

University costs

I do not foresee any costs for the University over and above the cost of time from input from my academic supervisor.

Section 9: Any Other Relevant Information

Section 10: Key References

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Section 11: Confirmation of Supervisors’ Approval

“I confirm that both my Academic and Clinical Supervisors have seen and approved this research proposal and have both completed the supervisors’ appraisal forms below.”
Delete as appropriate

| | |
|-----|--|
| Yes | |
|-----|--|

Appendix 1

Main Academic Supervisor’s Appraisal of Project Risk

| |
|--------------------------|
| Supervisor’s Name |
| Nuno Ferreira |

| |
|-------------|
| Date |
| 17.10.16 |

| | | |
|---|--|--|
| Do you consider that the project should proceed in broadly its current form? <i>Delete as appropriate</i> | | |
| Yes | | |

| |
|--|
| Outline the reasons for the above response Highlight any areas of risk to the completion of the project that have not been fully addressed within the proposal and any steps that could be taken to reduce risks |
| |

Appendix 2

Clinical Thesis Supervisor's Appraisal of Project Risk

| Supervisor's Name |
|------------------------|
| Dr Caroline Somerville |

| Position |
|-----------------------|
| Clinical Psychologist |

| Date |
|----------|
| 21/11/16 |

| Do you consider that the project should proceed in broadly its current form? <i>Delete as appropriate</i> | | |
|--|--|--|
| Yes | | |

| Outline the reasons for the above response Highlight any areas of risk to the completion of the project that have not been fully addressed within the proposal and any steps that could be taken to reduce risks |
|---|
| |