DOCTOR OF CLINICAL PSYCHOLOGY (DCLINPSY)

Research Portfolio Submitted in Part Fulfilment of the requirements for the Degree of Doctorate in Clinical Psychology

Caswell, Amy

Award date:
2018

Awarding institution:
University of Bath

DOCTOR OF CLINICAL PSYCHOLOGY (DCLINPSY)

Research Portfolio Submitted in Part Fulfilment of the requirements for the Degree of Doctorate in Clinical Psychology

Caswell, Amy

Award date:
2018

Awarding institution:
University of Bath

Research Portfolio Submitted in Part Fulfilment of the requirements for the Degree of Doctorate in Clinical Psychology

Amy J Caswell

Doctorate in Clinical Psychology

University of Bath
Department of Psychology

May 2018

Blank page

Word counts

Note, all word counts exclude abstracts, figures, tables and legends.

Literature review: 5339

Service Improvement Project: 4358

Main Research Project: 4392

Executive Summary of Main Research Project: 648

Connecting Narrative: 2883

Total: 17556

Declaration

I declare that the work presented in this thesis is my own and has not been submitted for any other degrees in this or in any other university or institute of learning.

Table of contents

Table of tables

Literature review

Service Improvement Project

Main Research Project

Table of figures

Literature review

Service Improvement Project

Main Research Project

Blank page

Abstracts

Literature review

Note – this abstract is longer than standard, to meet PRISMA guidelines required by the journal (BMJ).

Anxiety and depression are thought to be common in Chronic Fatigue Syndrome, although the reported prevalence of these difficulties varies between studies. These comorbidities are known to have implications for patient wellbeing and health, and there is some evidence that they might have implications for outcomes to treatment for Chronic Fatigue. The current review aimed to examine the prevalence of anxiety and depression, and to investigate whether these difficulties affect fatigue and physical function outcomes in available randomised controlled trials of NICE endorsed evidence-based treatment.

A systematic review, meta-analysis and meta-regression were completed. Published and unpublished (a) randomised controlled trials of (b) CBT or GET for (c) adults with (d) CFS, in which (e) post-intervention fatigue and/or physical function scores were reported, and (f) anxiety and/or depression scores were reported at baseline, were identified, from searches of three databases (Pubmed, Embase, PsycINFO) and reference lists of included studies and relevant reviews. Searches took place on 10th April 2017. Risk of bias was assessed using the Cochrane Risk of Bias tool. Estimates of depression and anxiety were summarised with a narrative review. Meta-regression models were used to explore whether anxiety and depression are associated with outcomes to treatment.

Nine papers were identified and included in the review. The analysis indicated that reported rates of anxiety and depression were heterogeneous between studies, but that up to 55% of participants experience comorbid depressive disorders, with 10-20% experiencing major depressive disorder, and that 10-48% of participants experience a comorbid anxiety disorder. Meta-regressions indicated that depressive symptoms were associated with less improvement in physical function following treatment (nine studies). Depression was not associated with fatigue outcomes; anxiety was not associated with either fatigue or physical function outcomes.

The findings have important implications for the support and treatment of patients with Chronic Fatigue Syndrome. For patients to receive the best possible care, it is imperative that clinicians and services address all presenting physical and

psychological needs, to optimise treatment outcomes. Patients experiencing comorbid depression may benefit from essential interventions aimed at addressing depressive symptoms before or alongside treatment for Chronic Fatigue to increase treatment response.

Service Improvement Project

Mind-maps are a graphical communication technique that has been found to enhance therapeutic work in substance misuse services. Despite their value in these settings, they have not been so frequently utilised in general mental health provision. To address this gap, a mind-map booklet, the "My Wellbeing Toolkit" was recently developed and introduced in an NHS Recovery Service. The current service improvement project aimed to explore uptake of the booklet and make recommendations for improvements to the booklet.

A three-stage sequential explanatory mixed methods study was used to explore the evaluation questions: the initial stage involved collecting data on the number of care coordinators who had used the booklet, from existing logs, the second stage involved collection of questionnaire data on usage patterns of the booklet, the third involved collection of qualitative data on experiences of using the booklet. Quantitative data was explored using descriptive statistics; qualitative data was analysed using thematic analysis.

Care coordinators identified that the booklet was useful for themselves and for clients, however uptake of the booklet was low. A number of barriers were identified: practical barriers, lack of confidence and clarity when using the booklet and a lack of client engagement. A series of recommendations were made to address these barriers and to improve the content of the booklet.

The project suggests that mind-map booklets have considerable value for mental health provision, however support needs to be provided to clinicians to facilitate their use. Future directions for research include exploring client experiences of mind-map based booklets.

Main Research Project

Cervical cancer patients are at particular risk of experiencing psychological distress and mental health difficulties. The current study investigated whether this is

associated with knowledge of the sexually-transmitted nature of HPV, exploring HPV-related shame, anxiety and low mood in women with cervical cancer.

110 women with cervical cancer completed a repeated measures study, during which they read information that HPV is (1) considered to be a sexually-transmitted virus and (2) very common. Participants completed measures of shame, mood and anxiety after each level of information.

The results indicated that information that HPV is sexually-transmitted is associated with experiences of shame. Increased shame was associated with depression, low mood, anxiety and poor wellbeing. Women with a history of depression and anxiety were at particular risk for experiencing high levels of shame.

The results indicate that women with cervical cancer experience high levels of shame related to HPV information. This has implications for how to support patients who are at risk of experiencing high levels of shame, particularly around HPV-information provision, identifying at-risk patients, and the psychological support of patients.

Literature Review - A systematic review and meta-regression of the prevalence and effects of anxiety and depression on Chronic Fatigue Syndrome treatment outcomes

Amy J Caswell

a.caswell@bath.ac.uk

Internal supervisor: Dr Jo Daniels

Word count: 5339

Date of report: 16th May 2018

Journal structure: BMJ (See Appendix A for guidelines; all formatting is in line with journal requirements)

Note: Journal requires numbered references – these have been changed to APA 6th formatting for the purposes of this portfolio, to meet university requirements and to maintain consistency throughout the portfolio.

Data from this project was presented as a poster presentation at the 2018 BABCP conference

Abstract

Anxiety and depression are thought to be common in Chronic Fatigue Syndrome, although the reported prevalence of these difficulties varies between studies. These comorbidities are known to have implications for patient wellbeing and health, and there is some evidence that they might have implications for outcomes to treatment for Chronic Fatigue. The current review aimed to examine the prevalence of anxiety and depression, and to investigate whether these difficulties affect fatigue and physical function outcomes in available randomised controlled trials of NICE endorsed evidence-based treatment.

A systematic review, meta-analysis and meta-regression were completed. Published and unpublished (a) randomised controlled trials of (b) CBT or GET for (c) adults with (d) CFS, in which (e) post-intervention fatigue and/or physical function scores were reported, and (f) anxiety and/or depression scores were reported at baseline, were identified, from searches of three databases (Pubmed, Embase, PsycINFO) and reference lists of included studies and relevant reviews. Searches took place on 10th April 2017. Risk of bias was assessed using the Cochrane Risk of Bias tool. Estimates of depression and anxiety were summarised with a narrative review. Meta-regression models were used to explore whether anxiety and depression are associated with outcomes to treatment.

Nine papers were identified and included in the review. The analysis indicated that reported rates of anxiety and depression were heterogeneous between studies, but that up to 55% of participants experience comorbid depressive disorders, with 10-20% experiencing major depressive disorder, and that 10-48% of participants experience a comorbid anxiety disorder. Meta-regressions indicated that depressive symptoms were associated with less improvement in physical function following treatment (nine studies). Depression was not associated with fatigue outcomes; anxiety was not associated with either fatigue or physical function outcomes.

The findings have important implications for the support and treatment of patients with Chronic Fatigue Syndrome. For patients to receive the best possible care, it is imperative that clinicians and services address all presenting physical and psychological needs, to optimise treatment outcomes. Patients experiencing comorbid depression may benefit from essential interventions aimed at addressing depressive

symptoms before or alongside treatment for Chronic Fatigue to increase treatment response.

Key words

Chronic Fatigue Syndrome; Anxiety; Depression; CBT; GET; Outcomes; Comorbidity.

Introduction

Chronic Fatigue Syndrome, also referred to as Myalgic Encephalomyelitis (CFS), is a severely disabling condition affecting 0.2%-2% of the general adult UK population. The condition is characterised by extreme fatigue and a range of other symptoms including cognitive impairment, pain and sleep difficulties (Nacul et al., 2011). As there is currently no universal agreement on the underpinning pathogenesis of the condition (NICE, 2007), present treatment focuses on management of symptoms and living well with CFS, with NICE guidelines recommending cognitive behavioural therapy (CBT), graded exercise therapy (GET) and activity management programmes as best care (NICE, 2007). However, response rates to these treatments are limited, with small to medium effect sizes at best (Castell, Kazantzis, & Moss-Morris, 2011; Larun, Brurberg, Odgaard-Jensen, & Price, 2015; Price, Mitchell, Tidy, & Hunot, 2008), with a number of patients reporting little or no improvement following treatment, and even worsening of symptoms (White et al., 2011).

Considering these unimpressive outcomes and the variable prognosis patients face, it is important to examine factors associated with both the quality of life of patients living with CFS and treatment outcomes, in order to optimise patient wellbeing and improve clinical outcomes. One factor that may have importance is comorbidity of anxiety and depression. Research suggests that comorbid anxiety and depression are common in CFS, above rates observed in the general population, with a recent small-scale study finding rates of anxiety and depression in CFS at 42.2% and 33.3% respectively (Daniels, Brigden, & Kacorova, 2017). However, estimates vary considerably and it is difficult to infer true prevalence (Kacorova, 2013). For example, studies report estimates of major depression ranging from 5.6% (Taylor & Jason, 1998) to 50% (Axe, Satz, Rasgon, & Fawzy, 2004), and estimates of anxiety ranging from ~20% (e.g. Farmer et al., 1995; Pepper, Krupp, Friedberg, Doscher, & Coyle, 1993) to ~52% (e.g. Millon et al., 1989; Wessely, Chalder, Hirsch, Wallace, & Wright, 1996). This problem has been contributed to by the varying diagnostic criteria and measurement of comorbidities applied in studies, nevertheless variability cannot entirely be attributed to measurement heterogeneity, with differences observed even when the same diagnostic criteria and measurement are applied (e.g. Cella, White, Sharpe, & Chalder, 2013; Nater et al., 2009).

Anxiety and depression are known to pose a particular risk for increased disability and symptomology, poor adjustment to illness and reduced quality of life in CFS (e.g. Cella, Sharpe, & Chalder, 2011; Cella et al., 2013; Moss-Morris, Sharon, Tobin, & Baldi, 2005). Indeed, in other long-term health conditions these comorbidities have been found to have a greater impact on the functional status and quality of life of patients than the level of severity of their physical illness (Eisner et al., 2010; Johnson, Jones, Seidenberg, & Hermann, 2004; Naylor et al., 2012). Research has suggested that the impact of anxiety and depression on wellbeing and disability in CFS may be associated with specific patterns of cognition and behaviour. In particular, anxiety has been found to be associated with beliefs about damage from CFS and hypervigilance and depression has been found to be associated with avoidance, hypervigilance to symptoms and catastrophising (Cella et al., 2013). While these thinking styles and behaviours are understandable in the context of a distressing and disabling condition which is so poorly understood, it is evident that, if we are to improve patient wellbeing, we need to fully understand the prevalence and impact of these comorbidities.

Beyond immediate quality of life, evidence suggests that these comorbidities likely also impact on treatment outcomes and prognosis (e.g. Flo & Chalder, 2014). There is emerging evidence that depressive symptoms may be associated with poorer outcomes to CBT (Flo & Chalder, 2014) and psychoeducation programs aimed at encouraging graded exercise (Bentall, Powell, Nye, & Edwards, 2002), suggesting depression might impact treatment engagement, adherence and response, similarly to other health conditions (DiMatteo, Lepper, & Croghan, 2000). There is currently a lack of research into whether anxiety symptoms are related to CFS treatment outcomes, with the only available paper failing to find a relationship (Flo & Chalder, 2014). However, a meta-analysis exploring other health conditions, found a variable impact of anxiety on treatment adherence (DiMatteo et al., 2000), suggesting that this relationship may be complex and require further research.

The above research suggests that comorbid anxiety and depression are likely common in CFS, with significant impact on the wellbeing and functional status of patients. Furthermore, there is emerging evidence that these comorbidities may impact on treatment outcome and prognosis, which is particularly important given the unimpressive outcomes to current recommended treatments for the condition.

However, the available literature is hampered by the heterogeneity of reported prevalence, and the limited research on the impact of these comorbidities on outcomes, particularly concerning anxiety. Furthermore, research has not established which outcomes these comorbidities may affect. Therefore, further data on the prevalence and influence of anxiety and depression on outcomes in CFS is needed to contribute to both clinical knowledge and treatment targets and to help clinicians to adapt and prioritise treatment accordingly.

Therefore, the current systematic review and meta-analysis has two aims. First, it aims to provide an accurate understanding of the prevalence of anxiety and depressive disorders in CFS. Secondly, it aims to examine whether anxiety and depression moderate the effectiveness of the current recommended treatments, CBT and GET, and explore whether this effect is specific to certain outcomes. The review aims to explore these questions by identifying published and unpublished randomised controlled trials of CBT or GET for adults with CFS, in which post-intervention fatigue and/or physical function scores are reported and anxiety and/or depression scores are reported at baseline.

It is intended that the review will provide an accurate understanding of the prevalence of these difficulties and how they might affect the effectiveness of treatment. This knowledge will inform best care and practice and ensure that patients' psychological needs are not left unmet.

Method

The study was registered on PROSPERO (ID CRD42016039813).

Search strategy

Published and unpublished trials were identified through systematic searches of Pubmed, Embase and PsycINFO, completed on 10th April 2017. Searches combined terms indicative of CFS, CBT and GET and randomised controlled trials, with UK and US spellings. Search terms identifying randomised controlled trials were tailored to each database following guidelines in the Cochrane handbook (2011): Embase (Lefebvre et al., 2011), Pubmed (sensitivity- and precision-maximizing version (2008 revision); Lefebvre et al., 2011), PsycINFO (Eady, Wilczynski, & Haynes, 2008). For full search terms, see Appendix B.

There were no additional limits placed on searches. The reference and citation lists of randomised controlled trials, systematic reviews and meta-analyses were also checked for additional trials.

Selection criteria

Published and unpublished (a) randomised controlled trials of (b) CBT or GET for (c) adults with (d) CFS, in which (e) post-intervention fatigue and/or physical function scores were reported, and (f) anxiety and/or depression scores were reported at baseline, were identified for possible inclusion in the review.

Details of PICO eligibility criteria are described below, as are details of requirements placed on studies for measuring baseline/moderator variables of depression and anxiety.

Selection criteria were adapted from Kacorova (2013).

Population/patient characteristics and setting. Trials of male and female participants over the age of 18 were included; trials of children and adolescents were not eligible for inclusion, as it has been suggested that they may represent a different pathology (Collin, Nuevo, van de Putte, Nijhof, & Crawley, 2015). Studies were included regardless of culture and setting, although papers had to be written in English. CFS was required to be assessed using the Centers for Disease Control (CDC) criteria, referred to as the Fukuda criteria (Fukuda et al., 1994) or the Oxford criteria (Sharpe et al., 1991), as the two primary criteria used in research; trials using equivalent criteria were also included. Studies including participants with physical health comorbidities that could account for CFS symptomology were excluded, in line with diagnostic criteria (Fukuda et al., 1994; Sharpe et al., 1991) and to prevent inclusion of participants who had been incorrectly diagnoses with CFS. Studies including participants with comorbid mental health diagnoses were included, providing the diagnosis was deemed secondary to CFS.

Intervention characteristics. Randomised controlled trials of CBT and GET in which a CFS-specific intervention was clearly described were included. Studies that did not apply a CFS-specific protocol were excluded, for example stress-management interventions. There were no restrictions on the length or duration of treatment, or the format of treatment, for example both individual and group-based

treatments were eligible for inclusion. For the purposes of the review, CBT or GET in combination with other interventions were not included, as the evidence base for these interventions is more limited (NICE, 2007).

Comparison/control characteristics. Studies were required to have a control group, which could include: (1) Standard medical management and care, including treatment as usual or waiting list (2) Pharmacological therapy (3) Non-CBT or GET psychological therapies, including relaxation or non-directive therapies; these psychological therapies were included as they contain none of the active components of treatment associated with CBT and GET.

If a study included multiple control groups, the condition that appeared to control best for therapist attention (Kendal, Holmbeck, & Verduin, 2004) was chosen as the comparison group.

Outcome measures. The principle outcome used in this review was fatigue, measured either as (1) Change in fatigue severity (continuous) as indexed by the Chalder Fatigue Scale (Chalder et al., 1993)**,** or any other validated, or clearly described, fatigue scale, or (2) Clinical recovery or change (dichotomous), based on defined cut-off on validated scales.

The secondary outcome was improvement in overall patient- or clinician-rated physical functioning.

Baseline/moderator variables. To be included in the review, depression and/or anxiety had to be assessed and reported at baseline using a recognised and validated measure or diagnostic criteria. Anxiety and depression diagnoses eligible for inclusion were decided through consultation with an expert in the field (JD), and consulting DSM-3, DSM-IV and ICD-10. General measures of wellbeing or distress were excluded.

Other considerations. If publications containing secondary analyses of previously-published data were identified, the primary report of the study was used. Secondary analyses were disregarded, unless the report provided additional data not available in the original publication.

Data extraction and quality assessment

Following database searches, titles and abstracts of articles were retrieved and transferred to Covidence for assessment. Two investigators (AC and HW; 100% and 20% respectively) then checked abstracts against the above described eligibility criteria. Titles and abstracts which did not provide sufficient detail to check all inclusion criteria were met, but did not meet any exclusion criteria, were included for full review. Disagreements were resolved through discussion with JD, a senior investigator and expert in the field; see Appendix D. Full texts of potentially relevant articles were then screened (AC and HW, 100% and 20% respectively), using a standardised form; borderline papers were again discussed and resolved with JD. Data extraction was completed by AC, using the extraction form, before meta-analysis.

When papers were ambiguous, or data were insufficient, authors were contacted. Authors were requested to provide additional data if a study met all requirements other than reporting anxiety or depression data at baseline; if an author was unable to provide said data, the study was not included within the analysis. Authors were also contacted to clarify the lower age limit of participants, if unclear; if authors did not respond, the paper was included, unless the paper referenced the inclusion of adolescents or children. Finally, leading authors in the field were contacted to provide any unpublished data. For a full list of contacted authors, see Appendix C.

Several aspects of the included studies were assessed and recorded, including study characteristics, such as number of participants randomised to the study, total number of treatment arms (although all treatment arms were not necessarily included in the analysis) and country. Participant characteristics were also recorded, including CFS diagnostic criteria, lower age range of participants and the number of female participants. Aspects of treatment, including whether the study applied a CBT or GET intervention, whether the intervention was individual or group-based and number of sessions, were recorded, as was the type of control group. Finally, Fatigue and Physical function outcome measures were recorded, as were measures of anxiety and depression at baseline (see Appendix E for extraction form).

Risk of bias in individual studies was assessed with the Cochrane risk of bias assessment tool, by AC and HW (resolved through agreement), which assesses seven domains of (1) random sequence generation (2) allocation concealment (3) blinding

of participants and personnel (4) blinding of outcome assessment (5) incomplete outcome data (6) selective reporting, and if there was evidence of (7) other bias. This information was summarised during data synthesis.

Data synthesis

Characteristics and results of all included studies were tabulated, including baseline rates of depression and anxiety, mean scores on measures of depression and anxiety, and post-intervention scores on measures of fatigue and physical functioning.

Selection and inclusion of studies. Numbers of retrieved and included studies were detailed. Inter-rater reliability for abstract screens and full texts was formally assessed using Gwet's AC1 statistic, calculated using AgreeStat version 2015.6.1 (Advanced Analytics LLC, Gaithersburg, MD, USA). Gwet's AC1 was preferred to the more widely-used Cohen's Kappa, as Kappa is sensitive to imbalances in trait prevalence in the subject population and can produce low estimates of chance-corrected agreement even when absolute agreement is high (Feinstein & Cicchetti, 1990; Gwet, 2002).

Study characteristics. Study characteristics were summarised using a narrative synthesis, presenting relevant details of included studies.

Prevalence of comorbid depression and anxiety in CFS sample. A narrative synthesis was used to explore the prevalence of depression and anxiety. Rates of anxiety and depression were identified, according to the number/percentage of participants meeting clinical cut-offs, according to validated measures, and/or diagnostic criteria within each paper.

Mean scores on measures of depression/anxiety within each paper were then summarised. If papers reported mean scores within groups, but not within the whole sample, sample means and SDs were calculated using available group means and SDs.

It was also recorded whether papers made exclusions based on depression and anxiety.

Effects of anxiety and depression on treatment outcomes: meta-analyses and meta-regression. While the focus of the current paper was not to complete a meta-analysis exploring the effectiveness of CBT and GET for CFS, (as this has been done before, (e.g. Castell et al., 2011; Larun et al., 2015; Price et al., 2008), initial

meta-analyses were performed to identify potential variability in effect sizes among the identified papers. Two random-effects meta-analyses were performed, using the inverse variance method to pool the effect sizes across studies. Random effects models were used as it is assumed differences in methods and sample characteristics among the sample studies result in heterogeneity in the true effects sizes. The first explored the effectiveness of psychotherapy on fatigue outcomes, and the second explored the effectiveness on physical function outcomes. Again, CBT and GET interventions were grouped, as there was not sufficient power to assess the interventions in separate models. For each meta-analysis, t^2 was calculated using the DerSimonian-Laird estimator, and the I^2 statistic, with 95% confidence intervals, and Q-statistic were used to assess heterogeneity in the effect sizes. I^2 values of around 25%, 50%, and 75% represent low, medium, and large values of heterogeneity, respectively (Higgins & Thompson, 2002). Funnel plots were examined for asymmetry in effect sizes (Sterne et al., 2011).

Four mixed-effect meta-regression models were then estimated to explore whether anxiety and depression could account for heterogeneity in effect sizes for fatigue and physical function outcomes. In each model anxiety or depression was included as the predictor variable, with fatigue or physical functioning as the outcome variable. As anxiety and depression had been reported on different scales for some studies, data were rescaled to standardise the date to the same metric. Given the small sample sizes, separate regressions were performed for anxiety and depression to preserve degrees of freedom and maximise power. Two papers were missing anxiety data at baseline, therefore including both depression and anxiety within one model would have resulted in significant loss of power for the depression variable.

Meta-analyses and meta-regressions were performed using the *metafor* package in R 3.4.3.

Calculation of effect sizes. All outcomes, except for fatigue outcomes reported in Wearden et al., (1998) were continuous, therefore standardised mean differences (Cohen's d) were calculated as the effect size. Effect sizes of 0.8 are considered large, while effect sizes of 0.5 are moderate, and effect sizes of 0.2 are considered small (Cohen, 1988). When multiple follow-up scores were reported, the

scores immediately post-intervention, or those closest to the end of the intervention were used.

For fatigue outcomes reported in Wearden et al. (1998) an odds ratio was calculated using the number of non-cases (no fatigue) post-treatment, which was then converted to a standardised mean difference.

White et al. (2011) contained independent CBT and GET treatment arms, therefore separate effect sizes of the effectiveness of CBT and GET were calculated; White et al. (2011) is consequently represented twice in each meta-analysis and regression.

Sharpe et al (1996) did not report standard deviations corresponding to post treatment and control means, and the author was unable to provide the data when contacted by email; effect sizes were therefore calculated using data provided in a published Cochrane review (Price et al., 2008).

Results

Selection and inclusion of studies

The systematic searches identified 1042 unique records. Of these 146 full texts were retrieved and read. 15 borderline papers were resolved and excluded through discussion: five papers were excluded for reporting general measure of psychological wellbeing/distress, but not a specific measure of anxiety/depression (Lopez et al., 2011; Prins et al., 2001; Tummers, Knoop, van Dam, & Bleijenberg, 2013; Vos-Vromans et al., 2016; Wiborg, van Bussel, van Dijk, Bleijenberg, & Knoop, 2015); seven were excluded for using a partial CBT intervention or combination treatment (Friedberg, Adamowicz, Caikauskaite, Seva, & Napoli, 2016; Nunez et al., 2011; Rimes & Wingrove, 2013; Surawy, Roberts, & Silver, 2005; Thomas, Sadlier, & Smith, 2006; Thomas, Sadlier, & Smith, 2008; Wearden et al., 2010); two were excluded for not including a suitable control condition (Burgess, Andiappan, & Chalder, 2012; Windthorst et al., 2017); one paper was excluded as the study had not excluded patients with relevant physical health comorbidities (Strang, 2002).

Nine studies were found to the meet criteria and are included in the review. See Figure 1 for Prisma flow diagram.

Absolute agreement among screeners was high at the abstract stage (93.6%), with a Gwet's AC1 value of 0.918 (95% CI 0.874, 0.962). Absolute agreement among

screeners was also high at the full text stage (82.7%), with a Gwet's AC1 value of 0.795 (95% CI 0.596, 0.995).

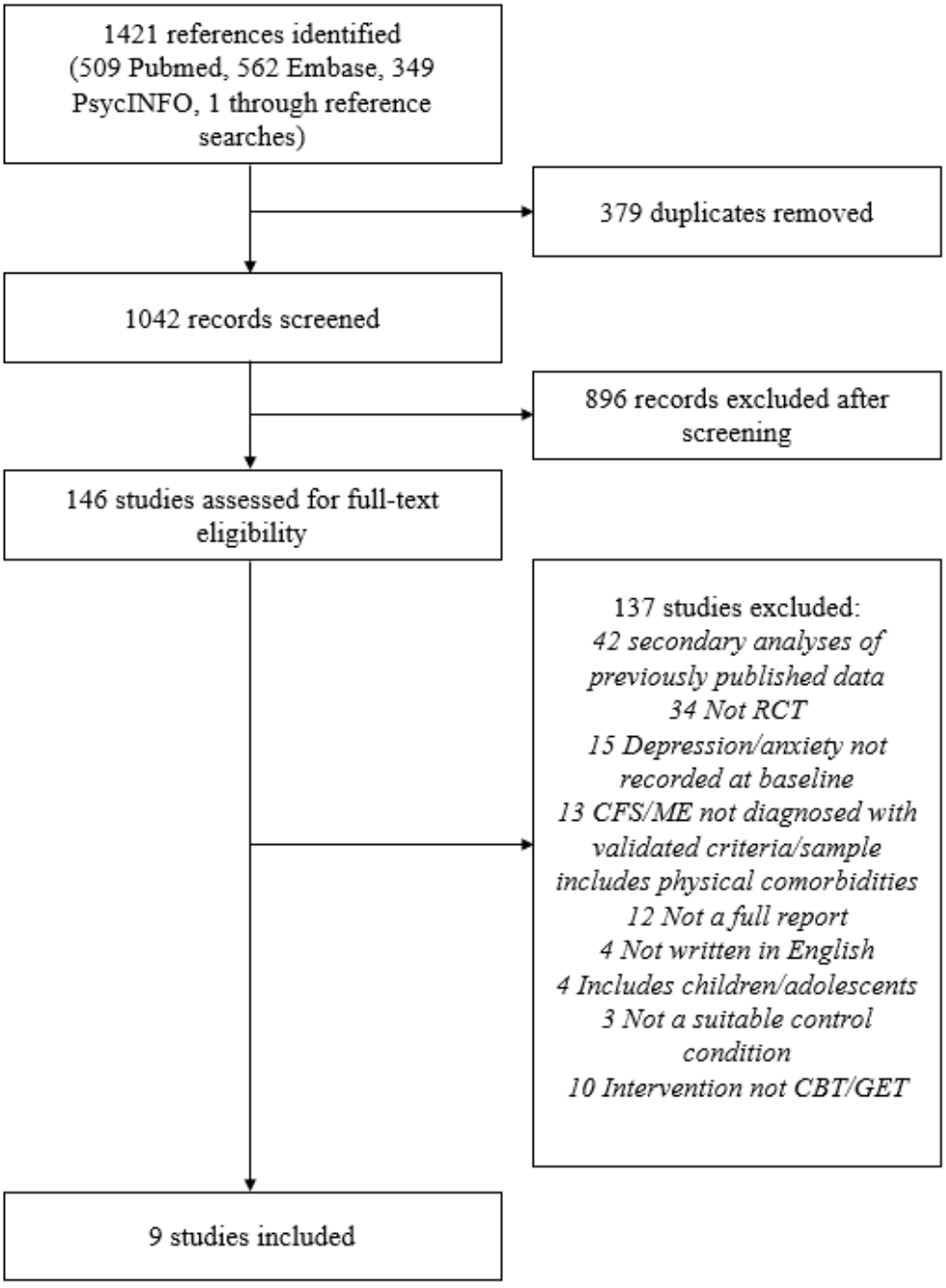


Figure 1. PRISMA flowchart showing study selection process

Characteristics of included studies

Characteristics of included studies (Barrett, 1992; Deale, Chalder, Marks, & Wessely, 1997; Fulcher & White, 1997; Jason et al., 2007; Moss-Morris et al., 2005; O'Dowd, Gladwell, Rogers, Hollinghurst, & Gregory, 2006; Sharpe et al., 1996; Wearden et al.,

1998; White et al., 2011) are shown in Table 1. The size of the studies varied from between 43 and 641 participants. Five studies applied a CBT intervention, three used GET, and one study (White et al., 2011) included both CBT and GET in two separate treatment arms.

Quality of included studies varied (see Figure 2), but several studies gave insufficient details to assess all aspects of quality.

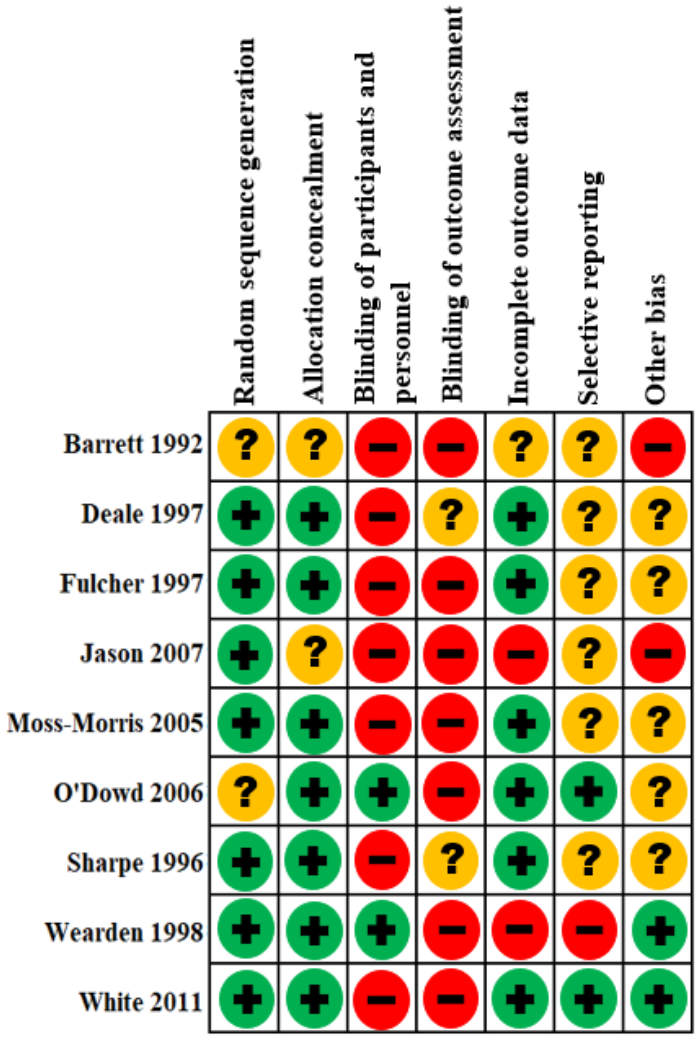


Figure 2. Figure showing quality of included studies

Table 1. Characteristic of included studies

	CFS diagnosis	C	Age	N (female)	Treatment arms	Intervention (N random)	Format	N sessions	Fatigue outcome	Phys Funct. outcome	Dep/anx	Control cond
Barrett 1992	Aus/Lloyd	Aus	18+	43 (30)	3	CBT (15)	Grp	9	POMS	sickness impact	BDI-I; STAI	EAS
Deale 1997	Oxford & CDC	UK	Adults	60 (41)	2	CBT (30)	Ind	13	Chalder	SF-36	BDI-I; n/a	Relax.
Fulcher 1997	Oxford	UK	Adults	66 (49)	2	GET (33)	Ind	12	Chalder	SF-36	HADS; HADS	Relax/ Flex
Jason 2007	Fuk/CDC	US	18+	114 (95)	4	CBT (29)	Ind	13	Krupp	SF-36	BDI-II; BAI	Relax.
Moss-Morris 2005	Fuk/CDC	NZ	18+	49 (34)	2	GET (25)	Ind	12	Chalder	SF-36	HADS; HADS	SMC
O'Dowd 2006	Fuk/CDC	UK	Adults	153 (2/3rds)	3	CBT (52)	Grp	8	Chalder	SF-36	HADS; HADS	EAS
Sharpe 1996	Oxford	UK	18+	60 (41)	2	CBT (30)	Ind	16	Likert	Karnofsky*	HADS; HADS	SMC
Wearden 1998	Oxford	UK	18+	136 (97)	4	GET (+drug placebo) (34)	Ind	8	Chalder	-	HADS; n/a	Exer. & drug plac.
White 2011 [a]	Oxford & Fuk	UK	18+	641 (485)	4	CBT (161)	Ind	15	Chalder	SF-36	HADS; HADS	SMC
White 2011[a]	Oxford & Fuk	UK	18+	641 (485)	4	GET (160)	Ind	15	Chalder	SF-36	HADS; HADS	SMC

**Results not included in analysis as SDs not reported, therefore authors were unable to calculate an effect size.*
C = Country study took place in; N (female) = Number of participants in the study (number of female participants); N (random) = Number randomised to treatment condition; N sessions = Number of sessions; Fatigue outcome = fatigue outcome measure; Phys Funct. outcome = physical function outcome measure; Dep/Anx = depression and anxiety measure used within the study; Control cond = Control condition.
Aus/Lloyd = Australian/Lloyd critera; Fuk/CDC = Fukuda/CDC criteria; CBT = Cognitive Behaviour Therapy; GET = Graded Exercise Therapy; Grp = Group format; Ind = Individual format; POMS = Profile of Mood States Questionnaire; Krupp = Krupp Fatigue Scale; Chalder = Chalder Fatigue Scale; SF-36 = 36-Item Short Form Health Survey; BDI-I = Beck Depression Inventory, version I; HADS = Hospital Anxiety and Depression Scale; BDI-II = Beck Depression Inventory, version II; EAS = Education and Support; Relax = Relaxation; Relax/Flex = Relaxation and Flexibility; SMC = Standard Medical Care; Exer & Drug plac = Exercise placebo and drug placebo.
a White 2011 included two treatments – CBT and GET, therefore White has been included twice

Participants

Participant information was inconsistently presented between studies. Age and gender are reported in Table 1. Seven papers reported work/employment status of participants (Barrett, 1992; Deale et al., 1997; Fulcher & White, 1997; Jason et al., 2007; Moss-Morris et al., 2005; Sharpe et al., 1996; Wearden et al., 1998); samples included ranged from 24.6-60% of participants being on disability benefits; 22.4-70% of participants were unemployed.

Three papers (Moss-Morris et al., 2005; Wearden et al., 1998; White et al., 2011) reported the median duration of illness of their full sample, which ranged from a median of 28-37 months. One paper (Barrett, 1992) reported participants had a mean duration of 98 months; one paper (O'Dowd et al., 2006) specified that 49% of participants had experienced symptoms for "more than 5 years".

Prevalence of comorbid depression and anxiety in CFS sample

Eight papers reported that they had excluded participants with concurrent severe depression and/or anxiety from participating in their study; see Table 2 for details.

With regards to the prevalence of depression and anxiety according to diagnostic criteria or clinical cut-offs, seven of the nine papers reported the prevalence of clinical depression in their sample. While measurement of depression varied, rates ranged from 10-20% of patients meeting criteria for major depression, and 8-55% met criteria for "any depressive disorder". Six of the nine papers reported the prevalence of clinical anxiety within their sample. While measurement of anxiety also varied, rates ranged from 10-48% of patients meeting criteria for "any anxiety disorder" (see Table 2 for full depression and anxiety prevalence data).

Table 2. Table showing rates of depression and anxiety reported in included studies

Paper	Study exclusions based on depression or anxiety?	Depression		Anxiety	
		Assessment instrument	Prevalence	Assessment instrument	Prevalence
Barrett 1992	Yes – participants with concurrent severe depressive disorder were excluded	-	Not stated	-	Not stated
Deale 1997	Yes – participants with concurrent severe depression were excluded	SADS – DSM-III-R	8% met diagnosis of dysthymia 15% met diagnosis of major depression An additional 10% had a diagnosis of both anxiety and depression	SADS – DSM-III-R	5% had anxiety disorder An additional 10% had a diagnosis of both anxiety and depression
Fulcher 1997	Yes – participants with any current psychiatric disorder, except simple phobia were excluded	-	Not stated	-	Not stated
Jason 2007	Yes – participants with melancholic depression or bipolar depression were excluded	SCID – DSM-IV	Depression and anxiety described as "most common" psychiatric comorbidities (62.3% had a lifetime Axis I diagnosis, and 38.6% had a current Axis I diagnosis)	SCID – DSM-IV	Depression and anxiety described as "most common" psychiatric comorbidities (62.3% had a lifetime Axis I diagnosis, and 38.6% had a current Axis I diagnosis)
Moss-Morris 2005	No	HADS	17% fell into the possible depressive disorder category. 13% fell into the probable depressive disorder category.	HADS	29% participants fell into the possible anxiety disorder category. 13% into the probable anxiety disorder category.
O'Dowd 2006	Unclear – participants with "concurrent severe mental illness, eg psychosis" excluded	HADS	21% had clinical levels of depression. 22% had borderline levels of depression	HADS	38% had clinical levels of anxiety. 33% had borderline levels of anxiety
Sharpe 1996	Yes – participants with severe depression, bipolar affective disorder, or at risk of suicide were excluded	DSM-III-R	20% had major depressive disorder 55% had any depressive disorder	DSM-III-R	48% had any anxiety disorder
Wearden 1998	Yes – participants with bipolar disorder or current suicidal ideation were excluded	SCID – DSM-III-R	10% met criteria for major depression 24% met criteria for either dysthymia or depressive disorder not otherwise specified	SCID – DSM-III-R	10% met criteria for an anxiety disorder
White 2011	Yes – Oxford criteria excludes patients with bipolar disorder.	SCID – DSM-IV	34% met criteria for any depressive disorder	SCID – DSM-IV	Not specified (47% of sample met criteria for any psychiatric disorder, including anxiety disorders)

SADS = Schedule for Affective Disorders and Schizophrenia; SCID = Structured Clinical Interview for DSM Disorders: DSM-III-R = Diagnostic and Statistical Manual of Mental Disorders, Third edition, Revised; DSM-IV = Diagnostic and Statistical Manual of Mental Disorders, Fourth edition; HADS = Hospital Anxiety and Depression Scale

With regards to baseline scores on measures of depression and anxiety, all nine papers reported baseline scores on a questionnaire measure of depression; 8 papers reported means, one reported median scores. These ranged from 14.35-18.66 on the BDI, and 6.19-8.77 on the HADS. See Table 3 for details. Seven of the nine papers reported baseline scores on a questionnaire measure of anxiety; 6 papers reported means, one reported median scores. These ranged from 6.94-8.39 on the HADS. See Table 3 for details.

Table 3. Table showing mean depression and anxiety scores reported in included studies

	Depression		Anxiety	
Paper	**Assessment instrument**	**Mean score**	**Assessment instrument**	**Prevalence**
Barrett 1992	BDI-I	14.46 (7.85)	A-State scale	43.78(13.92)
Deale 1997	BDI-I	14.35 (6.65)	-	-
Fulcher 1997	HADS	5*	HADS	4.75*
Jason 2007	BDI-II	18.66 (9.74)	BAI	12.58 (7.90)
Moss-Morris 2005	HADS	6.19 (1.70)	HADS	6.94 (3.44)
O'Dowd 2006	HADS	8.70 (3.52)	HADS	10.29 (4.18)
Sharpe 1996	HADS	6.75 (3.6)	HADS	7.35 (4.25)
Wearden 1998	HADS	8.77 (3.50)	-	-
White 2011	HADS	8.15 (3.78)	HADS	8.02 (4.25)

**Median reported as means not available.*
BDI-I = Beck Depression Inventory, version I; HADS = Hospital Anxiety and Depression Scale; BDI-II = Beck Depression Inventory, version II; A-State scale = Anxiety State Scale; BAI = Beck Anxiety Inventory

Effects of anxiety and depression on treatment outcomes: meta-analyses and meta-regression

The effects of CBT and GET on fatigue were compared with a control group in nine studies, with ten comparisons [as White et al (2011) included both CBT and GET comparisons]. Psychotherapy was found to reduce fatigue [SMD = 0.423, p<.001 (95% CI 0.274, 0.572)], see Figure 3. Between study heterogeneity was low [I^2 = 17.8% (0.0%, 58.8%)] and the Q test was not statistically significant, $\chi 2$ (9) = 10.94, p = .280. However, Huedo-Medina et al. (2006) note that the Q test is underpowered when fewer than 20 studies are included in the meta-analysis.

Inspection of the funnel plot (Figure 4) indicated some asymmetry.

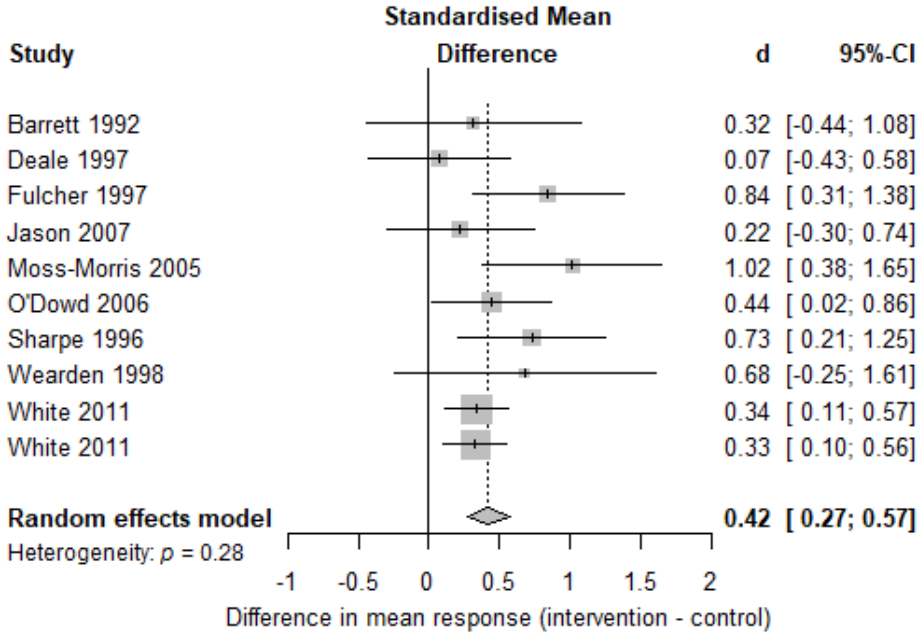


Figure 3. Scatterplot showing fatigue effect sizes of studies

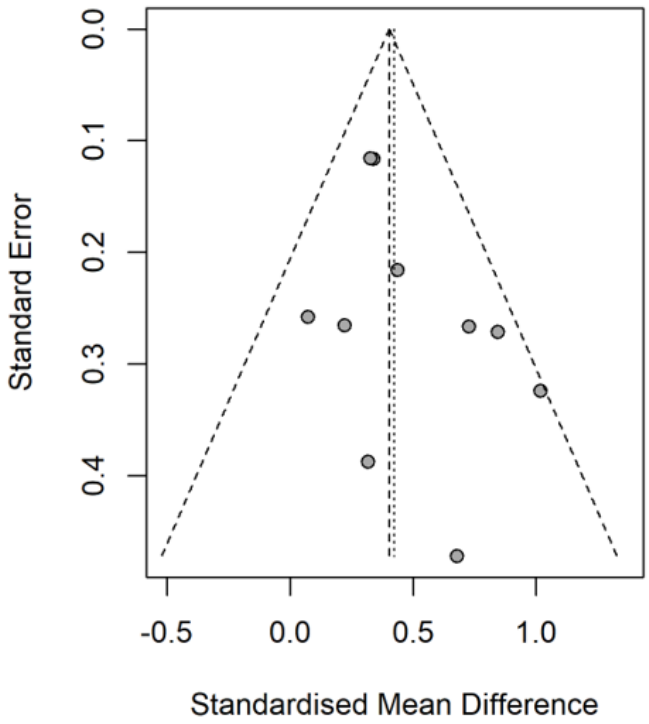


Figure 4. Funnel plot of standardised mean differences and standard error for fatigue outcomes

The effects of CBT and GET on physical functioning were compared with a control group in 8 studies. Psychotherapy was found to improve physical functioning [SMD 0.347, p<.001 (95% CI 0.174, 0.520)], see Figure 5. Heterogeneity was low [I^2 = 30.7% (0.0%, 69.1%)] and the Q test was not significant, $\chi 2$ (7) = 10.10, p = .183. Inspection of the funnel plot (Figure 6) indicated some asymmetry.

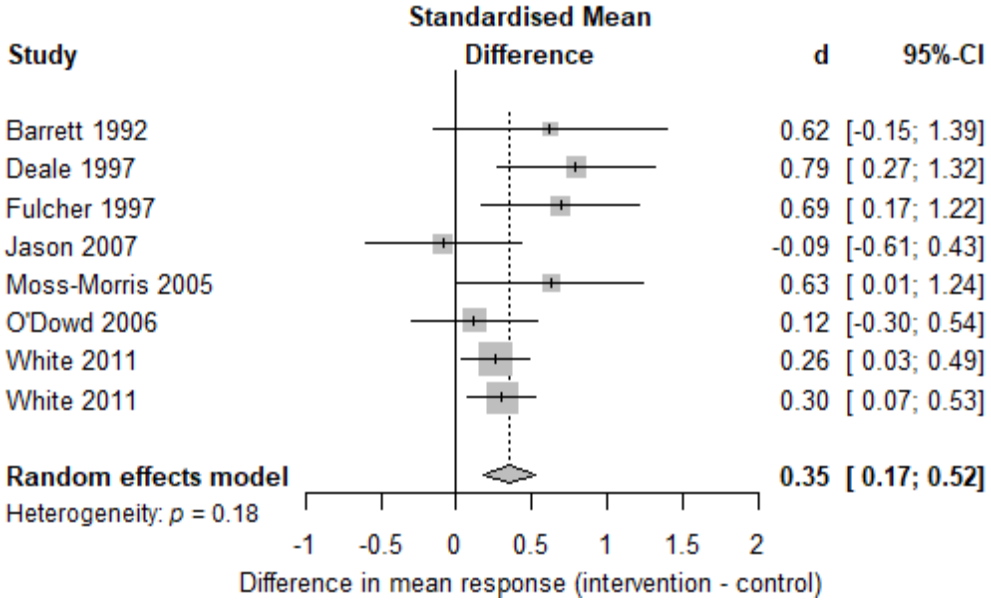


Figure 5. Scatterplot showing fatigue effect sizes of studies

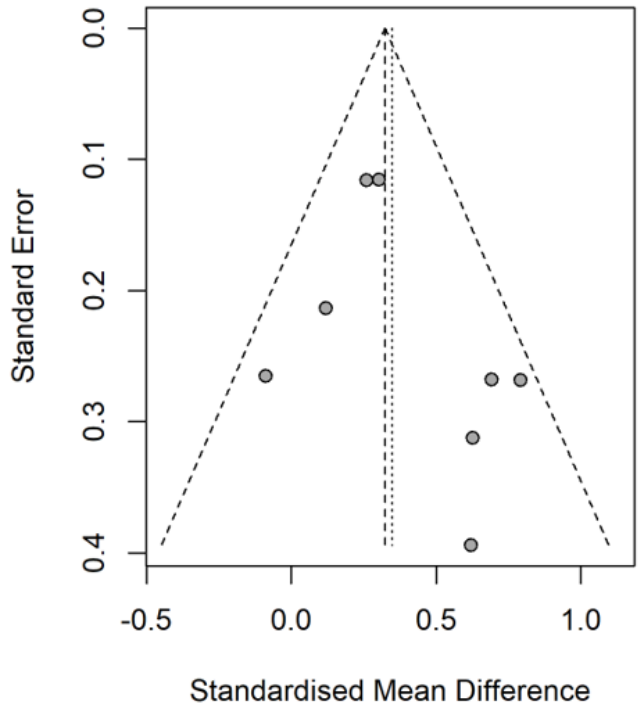


Figure 6. Funnel plot of standardised mean differences and standard error for fatigue outcomes

Meta-regression

Depression severity was associated with less improvement in physical functioning to therapy: studies reporting higher baseline depression scores reported lower effect sizes of treatment, B = -0.112, *p* = .030, (95% CI -0.214, -0.011). The pseudo R^2 value indicated that depression severity explained all the variance in the effect sizes; however, there is evidence that pseudo R^2 is unreliable when the number of studies is small (Lopez-Lopez, Marin-Martinez, Sanchez-Meca, Van den Noortgate, & Viechtbauer, 2014).

Depression was not associated with changes in fatigue and anxiety scores were not associated with any change in fatigue or physical functioning, see Table 4.

Table 4. Table showing B, SE B, 95% CIs and p values for the four regression models.

	Fatigue				Physical function			
Moderator	B	SE	*p*	95% CI	B	SE	*p*	95% CI
Depression	-0.03	0.05	.55	[-.13, .07]	**-0.11**	**0.05**	**.03**	**[-.21, -.01]**
Anxiety	-0.04	0.05	.44	[-.13, .06]	-0.02	0.05	.66	[-.11,.07]

Discussion

The current review set out to provide an accurate understanding of the prevalence of anxiety and depressive disorders in Chronic Fatigue Syndrome, and to explore whether these comorbidities affect treatment outcomes for CFS, with an aim to contribute to both clinical knowledge and treatment targets and help clinicians to adapt and prioritise treatment accordingly. These aims were addressed through a systematic review, meta-analysis and meta-regressions. The results indicated that comorbid anxiety and depression are common in CFS, and, importantly, that severity of depressive symptoms is significantly associated with poorer improvement in physical functioning following treatment. There was no association between anxiety and treatment outcomes, nor an association between depression and fatigue outcomes.

The included studies indicated that up to 55% of participants experienced comorbid depressive disorders, with 10-20% experiencing major depressive disorder. As all but one study made exclusions based on depressive and other disorders, it is likely that these estimates may even be conservative, and the true prevalence may be considerably higher. The values reported, suggest that rates of major depression appear to be two- to eight-fold those observed in the general population (estimates suggest 1-week prevalence rates of 2.3%, and that 4% to 10% of the general population will experience major depression during their lifetime (NICE, 2011) and are equivalent to those observed in a number of other conditions, including cancer (0%-58%) cardiovascular disease (range 20-50%) (Naylor et al., 2012) and diabetes (Anderson, Freedland, Clouse, & Lustman, 2001). The review also found that included studies reported 10-48% of participants as experiencing a comorbid anxiety disorder (any anxiety disorder), again comparable to levels seen in other conditions such as cancer (Linden, Vodermaier, Mackenzie, & Greig, 2012), and considerably higher than observed in the general population (where lifetime estimates suggest 5.7% will experience generalised anxiety disorder, 1.4% panic disorder, 12.1% social anxiety disorder) (NICE, 2011). These findings support those of a previous, unpublished, systematic review identifying that anxiety and depressive disorders are common (Kacorova, 2013).

The results of the meta-regression indicated that depression is associated with outcomes to treatment, with severity of depressive symptoms found to be associated with less improvement in physical functioning from treatment. This result provides compelling evidence that depressive symptoms may be associated with poor outcomes to treatment, providing new weight to previous research (Bentall et al., 2002; Flo & Chalder, 2014). The findings further current knowledge, suggesting that this relationship may be specific to physical functioning outcomes, as a relationship between depression and fatigue was not identified.

The findings have implications for the support and treatment of patients. It is known that CFS patients often face a variable prognosis, with recommended treatments having limited outcomes and focusing on management of symptoms, rather than treatment of the underlying pathogenesis of the condition, which is yet to be established. It is therefore important to understand factors associated both with quality of life of patients living with CFS, and factors associated with treatment outcomes.

These findings provide new evidence of the prevalence of anxiety and depression in Chronic Fatigue. It is already known that patients experiencing comorbid anxiety and depression are particularly vulnerable, being at risk of increased symptomology and disability, experiencing poor adjustment to illness and reduced quality of life (e.g. Cella et al., 2011; Cella et al., 2013; Moss-Morris et al., 2005). The review suggests that instead of viewing comorbidities as the exception, they should be treated as commonplace, and should be routinely assessed in clinical practice. These results indicate that, for patients to experience the highest quality of life, it is imperative that support adequately considers anxiety and depression and does not leave these needs unmet.

The finding that depressive symptoms are associated with poorer improvement in physical function following treatment, has important implications for the treatment of patients experiencing comorbid depression. While it is not possible to infer causation or the mechanisms by which depression is associated with outcomes, these findings indicate that patients with depressive symptoms may benefit significantly from adapted interventions aimed at reducing depression, either concurrently or prior to any treatment for CFS. The new finding that this relationship is specific to physical function outcomes and not fatigue, has particular importance as depression is known to lead to reductions in engagement and activity (e.g. Lewinsohn & Graf, 1973); in the case of CFS, it is possible that this might exacerbate any experiences of physical muscle deconditioning associated with reduced activity (Clark & White, 2005; Thyfault & Booth, 2011). Depression is also associated with low mood, lack of positive affect, loss of interest and enjoyment (American Psychiatric Publishing, 2013), all of which may be barriers to engaging in treatment, and is also associated with poor sleep (Nutt, Wilson, & Paterson, 2008) known to be problematic in CFS (Krupp, Jandorf, Coyle, & Mendelson). Together, this suggests that depression should be targeted from the point of assessment, and clinicians should consider placing the emphasis more on behavioural aspects of the CBT intervention, mirroring successful depression interventions such as behavioural activation (Veale, 2018) to engage the patient and commence physical reconditioning and improve physical functioning.

Interestingly, the study did not find evidence of anxiety moderating outcomes to treatment for CFS. This finding furthers previous research, which has failed to find evidence of an association between anxiety and CFS outcomes (Flo & Chalder, 2014),

and evidence that the association between anxiety and treatment outcomes in other health conditions is variable (DiMatteo et al., 2000). However, it is possible that the lack of relationship is in part attributable to the measurement of anxiety in the included papers, with all studies including non-specific measures of anxiety (five papers used the HADS, one used the BAI and the seventh used the A-State scale). It is known that anxiety is heterogeneous, consisting of multiple subtypes (American Psychiatric Publishing, 2013) and future research needs to explore whether specific anxiety disorders may be detrimental to outcome. For example, emerging research indicates that health anxiety is significantly associated with physical functioning (not fatigue) and furthermore, accounts for a significant proportion of the variance in physical function (Daniels & Salkovskis, in preparation).

The current review has several strengths. It is the first systematic review to explore the prevalence of anxiety and depression across studies, and the first to report findings from meta-regressions exploring anxiety and depression as moderators of outcomes. It differentiates between different outcomes, exploring how comorbidities affect fatigue and physical function outcomes. It therefore makes a significant contribution to the knowledge base and advances our clinical understanding of the support and treatment of patients with CFS.

There are also limitations to the current review that need to be considered. As only nine papers met the inclusion criteria, the meta-analyses and regressions were underpowered. While there was sufficient power to detect the relationship between depressive symptoms and physical function, the analysis might not have had sufficient power to detect any further relationships between anxiety and depressive symptoms and outcomes to treatment. In addition, baseline depression and anxiety scores were rescaled for inclusion in the regression models, to ensure they were on comparable scales. While this was unavoidable, it may have introduced sources of error as it is known the scales are not directly convertible (e.g. Applied Health Sciences (Mental Health), 2011) possibly resulting in heterogeneity of baseline variables. Furthermore, due to issues of power, trials of CBT and GET were combined within analyses; it is possible that the impact of anxiety and depression may be specific to certain treatments, leading us to have underestimated the impact in the current analysis. The funnel plots also indicated some asymmetry, suggesting there may be possible publication bias in the included studies.

There are further considerations that should be raised. The Cochrane risk of bias tool was chosen as the measure of quality assessment as it is provides a comprehensive assessment of bias in randomised clinical trials. However, the tool has limitations when applied to psychological research, including its lack of consideration of important issues such as treatment fidelity, and focus on other aspects such as blinding which are difficult in psychological research (Munder & Barth, 2018). A tool which explicitly considers features specific to psychological research may have been a useful addition to the review. An additional consideration is that the control group eligibility criteria included standard medical management and care, pharmacological therapy and non-CBT or GET psychological therapies, including relaxation or non-directive therapies. While a strength of the review is that the control group that best accounted for therapist attention was selected, to be able to specify the active treatment effect, it is possible that these varied control conditions had implications for the results. Importantly, three of the included studies used relaxation as the control condition. It is possible that relaxation may have had an effect on comorbid anxiety, possibly increasing the effectiveness of the control group if anxiety is associated with treatment outcomes. A final consideration is the inclusion of CBT and GET as the only two interventions of interest. These interventions were selected as they have the clearest empirical evidence of benefit, with there currently being insufficient evidence to recommend any other treatments (NICE, 2007). Given the context of the limited effectiveness of treatment, it is important that interventions with the best available evidence are explored to identify factors that may increase clinical effectiveness. Should an evidence base develop for other treatments, it may be useful to extend the current review to consider these interventions.

The review raises several recommendations and future directions for both clinical practice and research. With regards to clinical practice, as previously described, the results suggest comorbidities should be anticipated and should be routinely assessed in clinical practice. While anxiety was not associated with treatment outcomes, previous research has highlighted it is associated with poor quality of life and symptom worsening, and therefore should be considered in patient care. For patients to experience the highest quality of life and to receive high quality care, it is imperative that support adequately considers anxiety and depression and meets these needs. With regards to future directions for research, as the current analysis explores

the relationship between depression and anxiety at a meta-, rather than individual-level, further research is needed if we are to fully understand the mechanisms by which depression affects treatment. Treatment trials should routinely index baseline depression and specific anxiety and assess the impact of these on treatment engagement, adherence and specific outcomes. This should be explored at the treatment-specific level, to explore whether the impact of comorbidities differs between treatment types. Supporting this, there is a need for consistent measurement of anxiety and depression if we are to accurately understand the impact of these comorbidities on treatment and outcomes. The recent introduction of the consistent use of the Hospital Anxiety and Depression Scale (Zigmond & Snaith, 1983) in the national dataset should go some way to resolve this, however the HADS is not without criticism (Cosco, Doyle, Ward, & McGee, 2012) and it is unclear whether it has diagnostic accuracy (Thombs et al., 2016) and, importantly, does not measure specific types of anxiety.

In conclusion, this systematic review and meta-analysis provides evidence that comorbid depressive and anxiety disorders are common in Chronic Fatigue Syndrome. Severity of depression was found to be associated with poor treatment outcomes for physical functioning. The results have important implications for the wellbeing of patients, the identification of comorbid mental health difficulties, and the treatment of Chronic Fatigue.

References

American Psychiatric Publishing. (2013). *Diagnostic and statistical manual of mental disorders* (5th edition ed.). Arlington, VA: American Psychiatric Publishing.

Anderson, R. J., Freedland, K. E., Clouse, R. E., & Lustman, P. J. (2001). The Prevalence of Comorbid Depression in Adults With Diabetes. *A meta-analysis, 24*(6), 1069-1078. doi: 10.2337/diacare.24.6.1069

Applied Health Sciences (Mental Health), U. o. A. (2011). Assessing the validity of the PHQ-9, HADS, BDI-II and QIDS-SR in measuring severity of depression in a UK sample of primary care patients with a diagnosis of depression. In N. Q. I. Scotland (Ed.).

Axe, E. K., Satz, P., Rasgon, N. L., & Fawzy, F. I. (2004). Major Depressive Disorder in Chronic Fatigue Syndrome: A CDC Surveillance Study. *Journal of Chronic Fatigue Syndrome, 12*(3), 7-23. doi: 10.1300/J092v12n03_02

Barrett, E. A. (1992). *Cognitive-behavoiour therapy in the management of chronic fatigue syndrome.* (Master of Psychology), University of Sydney.

Bentall, R. P., Powell, P., Nye, F. J., & Edwards, R. H. (2002). Predictors of response to treatment for chronic fatigue syndrome. *Br J Psychiatry, 181*, 248-252.

Burgess, M., Andiappan, M., & Chalder, T. (2012). Cognitive behaviour therapy for chronic fatigue syndrome in adults: Face to face versus telephone treatment-A randomized controlled trial. *Behavioural and Cognitive Psychotherapy, 40*(2), 175-191. doi: 10.1017/S1352465811000543

Castell, B. D., Kazantzis, N., & Moss-Morris, R. E. (2011). Cognitive Behavioral Therapy and Graded Exercise for Chronic Fatigue Syndrome: A Meta-Analysis. *Clinical Psychology: Science and Practice, 18*(4), 311-324. doi: doi:10.1111/j.1468-2850.2011.01262.x

Cella, M., Sharpe, M., & Chalder, T. (2011). Measuring disability in patients with chronic fatigue syndrome: reliability and validity of the Work and Social Adjustment Scale. *J Psychosom Res, 71*(3), 124-128. doi: 10.1016/j.jpsychores.2011.02.009

Cella, M., White, P. D., Sharpe, M., & Chalder, T. (2013). Cognitions, behaviours and co-morbid psychiatric diagnoses in patients with chronic fatigue syndrome. *Psychol Med, 43*(2), 375-380. doi: 10.1017/s0033291712000979

Chalder, T., Berelowitz, G., Pawlikowska, T., Watts, L., Wessely, S., Wright, D., & Wallace, E. P. (1993). Development of a fatigue scale. *J Psychosom Res, 37*(2), 147-153.

Clark, L. V., & White, P. D. (2005). The role of deconditioning and therapeutic exercise in chronic fatigue syndrome (CFS). *Journal of Mental Health, 14*(3), 237-252. doi: 10.1080/09638230500136308

Cohen, J. (1988). *Statistical power analysis for the behavioural sciences* (2nd edition ed.). USA: Lawrence Erlbaum Associates

Collin, S. M., Nuevo, R., van de Putte, E. M., Nijhof, S. L., & Crawley, E. (2015). Chronic fatigue syndrome (CFS) or myalgic encephalomyelitis (ME) is different in children compared to in adults: a study of UK and Dutch clinical cohorts. *BMJ Open, 5*(10), e008830. doi: 10.1136/bmjopen-2015-008830

Cosco, T. D., Doyle, F., Ward, M., & McGee, H. (2012). Latent structure of the Hospital Anxiety And Depression Scale: a 10-year systematic review. *J Psychosom Res, 72*(3), 180-184. doi: 10.1016/j.jpsychores.2011.06.008

Daniels, J., Brigden, A., & Kacorova, A. (2017). Anxiety and depression in chronic fatigue syndrome/myalgic encephalomyelitis (CFS/ME): Examining the incidence of health anxiety in CFS/ME. *Psychol Psychother, 90*(3), 502-509. doi: 10.1111/papt.12118

Daniels, J., & Salkovskis, P. (in preparation). The prevalence and treatment of Chronic Fatigue Syndrome and co-morbid severe health anxiety.

Deale, A., Chalder, T., Marks, I., & Wessely, S. (1997). Cognitive behavior therapy for chronic fatigue syndrome: a randomized controlled trial. *Am J Psychiatry, 154*(3), 408-414. doi: 10.1176/ajp.154.3.408

DiMatteo, M. R., Lepper, H. S., & Croghan, T. W. (2000). Depression is a risk factor for noncompliance with medical treatment: meta-analysis of the effects of anxiety and depression on patient adherence. *Arch Intern Med, 160*(14), 2101-2107.

Eady, A. M., Wilczynski, N. L., & Haynes, R. B. (2008). PsycINFO search strategies identified methodologically sound therapy studies and review articles for use by clinicians and researchers. *J Clin Epidemiol, 61*(1), 34-40. doi: 10.1016/j.jclinepi.2006.09.016

Eisner, M. D., Blanc, P. D., Yelin, E. H., Katz, P. P., Sanchez, G., Iribarren, C., & Omachi, T. A. (2010). Influence of anxiety on health outcomes in COPD. *Thorax, 65*(3), 229-234. doi: 10.1136/thx.2009.126201

Farmer, A., Jones, I., Hillier, J., Llewelyn, M., Borysiewicz, L., & Smith, A. (1995). Neuraesthenia revisited: ICD-10 and DSM-III-R psychiatric syndromes in chronic fatigue patients and comparison subjects. *Br J Psychiatry, 167*(4), 503-506.

Feinstein, A. R., & Cicchetti, D. V. (1990). High agreement but low Kappa: I. the problems of two paradoxes. *J Clin Epidemiol, 43*(6), 543-549. doi: https://doi.org/10.1016/0895-4356(90)90158-L

Flo, E., & Chalder, T. (2014). Prevalence and predictors of recovery from chronic fatigue syndrome in a routine clinical practice. *Behav Res Ther, 63*, 1-8. doi: 10.1016/j.brat.2014.08.013

Friedberg, F., Adamowicz, J., Caikauskaite, I., Seva, V., & Napoli, A. (2016). Efficacy of two delivery modes of behavioral self-management in severe chronic fatigue syndrome. *Fatigue: Biomedicine, Health and Behavior, 4*(3), 158-174. doi: 10.1080/21641846.2016.1205876

Fukuda, K., Straus, S. E., Hickie, I., Sharpe, M. C., Dobbins, J. G., & Komaroff, A. (1994). The chronic fatigue syndrome: a comprehensive approach to its definition and study. International Chronic Fatigue Syndrome Study Group. *Ann Intern Med, 121*(12), 953-959.

Fulcher, K. Y., & White, P. D. (1997). Randomised controlled trial of graded exercise in patients with the chronic fatigue syndrome. *Bmj, 314*(7095), 1647-1652.

Gwet, K. (2002). Kappa Statistic is not Satisfactory for Assessing the Extent of Agreement Between Raters. *Series: Statistical Methods For Inter-Rater Reliability Assessment*.

Higgins, J. P. T., & Thompson, S. G. (2002). Quantifying heterogeneity in a meta-analysis. *Statistics in Medicine, 21*(11), 1539-1558. doi: doi:10.1002/sim.1186

Huedo-Medina, T., Sanchez-Meca, J., Marin-Martinez, F., & Botella, J. (2006). Assessing heterogeneity in meta-analysis: Q statistic or I2 index? *CHIP Documents. 19.*

Jason, L. A., Torres-Harding, S., Friedberg, F., Corradi, K., Njoku, M. G., Donalek, J., . . . Papernik, M. (2007). Non-pharmacologic interventions for CFS: A

randomized trial. *Journal of Clinical Psychology in Medical Settings, 14*(4), 275-296. doi: 10.1007/s10880-007-9090-7

Johnson, E. K., Jones, J. E., Seidenberg, M., & Hermann, B. P. (2004). The relative impact of anxiety, depression, and clinical seizure features on health-related quality of life in epilepsy. *Epilepsia, 45*(5), 544-550. doi: 10.1111/j.0013-9580.2004.47003.x

Kacorova, A. (2013). *Examining common mental health problems in chronic fatigye syndrome (CFS/ME): A two-part study.* (Masters Degree), University of Bath.

Kendal, P. C., Holmbeck, G., & Verduin, T. (2004). Methodology, design, and evaluation in psychotherapy research. In M. J. Lambert (Ed.), *Handbook of psychotherapy and behavior change* New York: John Wiley.

Krupp, L. B., Jandorf, L., Coyle, P. K., & Mendelson, W. B. Sleep disturbance in chronic fatigue syndrome. *J Psychosom Res, 37*(4), 325-331. doi: 10.1016/0022-3999(93)90134-2

Larun, L., Brurberg, K. G., Odgaard-Jensen, J., & Price, J. R. (2015). Exercise therapy for chronic fatigue syndrome. *Cochrane Database Syst Rev*(2), Cd003200. doi: 10.1002/14651858.CD003200.pub3

Lefebvre, C., Manheimer, E., & Glanville, J. (Producer). (2011, 10th April 2017). Chapter 6: Searching for studies. *Cochrane Handbook for Systematic Reviews of Interventions.* .

Lewinsohn, P. M., & Graf, M. (1973). Pleasant activities and depression. *J Consult Clin Psychol, 41*(2), 261-268. doi: 10.1037/h0035142

Linden, W., Vodermaier, A., Mackenzie, R., & Greig, D. (2012). Anxiety and depression after cancer diagnosis: prevalence rates by cancer type, gender, and age. *J Affect Disord, 141*(2-3), 343-351. doi: 10.1016/j.jad.2012.03.025

Lopez-Lopez, J. A., Marin-Martinez, F., Sanchez-Meca, J., Van den Noortgate, W., & Viechtbauer, W. (2014). Estimation of the predictive power of the model in mixed-effects meta-regression: A simulation study. *Br J Math Stat Psychol, 67*(1), 30-48. doi: 10.1111/bmsp.12002

Lopez, C., Antoni, M., Penedo, F., Weiss, D., Cruess, S., Segotas, M.-C., . . . Fletcher, M. A. (2011). A Pilot study of Cognitive Behavioral Stress Management Effects on Stress, Quality of life, and Symptoms in Persons with Chronic Fatigue Syndrome. *J Psychosom Res, 70*(4), 328-334. doi: 10.1016/j.jpsychores.2010.11.010

Millon, C., Salvato, F., Blaney, N., Morgan, R., Mantero-atienza, E., Klimas, N., & Fletcher, M. A. (1989). A psychological assessment of chronic fatigue syndrome/chronic epstein-barr virus patients. *Psychology & Health, 3*(2), 131-141. doi: 10.1080/08870448908400373

Moss-Morris, R., Sharon, C., Tobin, R., & Baldi, J. C. (2005). A randomized controlled graded exercise trial for chronic fatigue syndrome: outcomes and mechanisms of change. *J Health Psychol, 10*(2), 245-259. doi: 10.1177/1359105305049774

Munder, T., & Barth, J. (2018). Cochrane's risk of bias tool in the context of psychotherapy outcome research. *Psychotherapy Research, 28*(3), 347-355. doi: 10.1080/10503307.2017.1411628

Nacul, L. C., Lacerda, E. M., Pheby, D., Campion, P., Molokhia, M., Fayyaz, S., . . . Drachler, M. L. (2011). Prevalence of myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS) in three regions of England: a repeated cross-sectional study in primary care. *BMC Med, 9*, 91. doi: 10.1186/1741-7015-9-91

Nater, U. M., Lin, J. M., Maloney, E. M., Jones, J. F., Tian, H., Boneva, R. S., . . . Heim, C. (2009). Psychiatric comorbidity in persons with chronic fatigue syndrome identified from the Georgia population. *Psychosom Med, 71*(5), 557-565. doi: 10.1097/PSY.0b013e31819ea179

Naylor, C., Parsonage, M., McDaid, D., Knapp, M., Fossey, M., & Galea, A. (2012). Long-term conditions and mental health: the cost of co-morbidities: The King's Fund and Centre for Mental Health.

NICE. (2007). Chronic fatigue syndrome/myalgic encephalomyelitis (or encephalopathy): diagnosis and management. Clinical guideline [CG53].

NICE (Producer). (2011, 20 Aril 2018). Common mental health disorders; Guidance and guidelines. Retrieved from http://www.nice.org.uk/guidance/cg123

Nunez, M., Fernandez-Sola, J., Nunez, E., Fernandez-Huerta, J. M., Godas-Sieso, T., & Gomez-Gil, E. (2011). Health-related quality of life in patients with chronic fatigue syndrome: group cognitive behavioural therapy and graded exercise versus usual treatment. A randomised controlled trial with 1 year of follow-up. *Clin Rheumatol, 30*(3), 381-389. doi: 10.1007/s10067-010-1677-y

Nutt, D., Wilson, S., & Paterson, L. (2008). Sleep disorders as core symptoms of depression. *Dialogues in Clinical Neuroscience, 10*(3), 329-336.

O'Dowd, H., Gladwell, P., Rogers, C. A., Hollinghurst, S., & Gregory, A. (2006). Cognitive behavioural therapy in chronic fatigue syndrome: a randomised controlled trial of an outpatient group programme. *Health Technol Assess, 10*(37), iii-iv, ix-x, 1-121.

Pepper, C. M., Krupp, L. B., Friedberg, F., Doscher, C., & Coyle, P. K. (1993). A comparison of neuropsychiatric characteristics in chronic fatigue syndrome, multiple sclerosis, and major depression. *J Neuropsychiatry Clin Neurosci, 5*(2), 200-205. doi: 10.1176/jnp.5.2.200

Price, J. R., Mitchell, E., Tidy, E., & Hunot, V. (2008). Cognitive behaviour therapy for chronic fatigue syndrome in adults. *Cochrane Database Syst Rev*(3), Cd001027. doi: 10.1002/14651858.CD001027.pub2

Prins, J. B., Bleijenberg, G., Bazelmans, E., Elving, L. D., de Boo, T. M., Severens, J. L., . . . van der Meer, J. W. (2001). Cognitive behaviour therapy for chronic fatigue syndrome: a multicentre randomised controlled trial. *Lancet, 357*(9259), 841-847. doi: 10.1016/s0140-6736(00)04198-2

Rimes, K. A., & Wingrove, J. (2013). Mindfulness-based cognitive therapy for people with chronic fatigue syndrome still experiencing excessive fatigue after cognitive behaviour therapy: a pilot randomized study. *Clinical Psychology & Psychotherapy, 20*(2), 107-117. doi: 10.1002/cpp.793

Sharpe, M., Hawton, K., Simkin, S., Surawy, C., Hackmann, A., Klimes, I., . . . Seagroatt, V. (1996). Cognitive behaviour therapy for the chronic fatigue syndrome: a randomized controlled trial. *Bmj, 312*(7022), 22-26.

Sharpe, M. C., Archard, L. C., Banatvala, J. E., Borysiewicz, L. K., Clare, A. W., David, A., . . . Lane, R. J. (1991). A report--chronic fatigue syndrome: guidelines for research. *Journal of the Royal Society of Medicine, 84*(2), 118-121.

Sterne, J. A. C., Sutton, A. J., Ioannidis, J. P. A., Terrin, N., Jones, D. R., Lau, J., . . . Higgins, J. P. T. (2011). Recommendations for examining and interpreting funnel plot asymmetry in meta-analyses of randomised controlled trials. *Bmj, 343*. doi: 10.1136/bmj.d4002

Strang, J. M. (2002). *Treatment of chronic fatigue syndrome: A cognitive-behavioral approach to enhance personal mastery.* (63), ProQuest Information & Learning, US.

Surawy, C., Roberts, J., & Silver, A. (2005). The Effect of Mindfulness Training on Mood and Measures of Fatigue, Activity, and Quality of Life in Patients with Chronic Fatigue Syndrome on a Hospital Waiting List: A Series of Exploratory Studies. *Behavioural and Cognitive Psychotherapy, 33*(1), 103-109. doi: 10.1017/S135246580400181X

Taylor, R. R., & Jason, L. A. (1998). Comparing the dis with the scid: Chronic fatigue syndrome and psychiatric comorbidity. *Psychology & Health, 13*(6), 1087-1104. doi: 10.1080/08870449808407452

Thomas, M., Sadlier, M., & Smith, A. (2006). The effect of Multi Convergent Therapy on the psychopathology, mood and performance of Chronic Fatigue Syndrome patients: A preliminary study. *Counselling & Psychotherapy Research, 6*(2), 91-99. doi: 10.1080/14733140600711955

Thomas, M. A., Sadlier, M. J., & Smith, A. P. (2008). A multiconvergent approach to the rehabilitation of patients with chronic fatigue syndrome: a comparative study. *Physiotherapy, 94*(1), 35-42. doi: 10.1016/j.physio.2007.04.013

Thombs, B. D., Benedetti, A., Kloda, L. A., Levis, B., Azar, M., Riehm, K. E., . . . Tonelli, M. (2016). Diagnostic accuracy of the Depression subscale of the Hospital Anxiety and Depression Scale (HADS-D) for detecting major depression: protocol for a systematic review and individual patient data meta-analyses. *BMJ Open, 6*(4), e011913. doi: 10.1136/bmjopen-2016-011913

Thyfault, J. P., & Booth, F. W. (2011). Lack of regular physical exercise or too much inactivity. *Curr Opin Clin Nutr Metab Care, 14*(4), 374-378. doi: 10.1097/MCO.0b013e3283468e69

Tummers, M., Knoop, H., van Dam, A., & Bleijenberg, G. (2013). Moderators of the treatment response to guided self-instruction for chronic fatigue syndrome. *J Psychosom Res, 74*(5), 373-377. doi: 10.1016/j.jpsychores.2013.01.007

Veale, D. (2018). Behavioural activation for depression. *Advances in Psychiatric Treatment, 14*(1), 29-36. doi: 10.1192/apt.bp.107.004051

Vos-Vromans, D. C., Smeets, R. J., Huijnen, I. P., Koke, A. J., Hitters, W. M., Rijnders, L. J., . . . Knottnerus, J. A. (2016). Multidisciplinary rehabilitation treatment versus cognitive behavioural therapy for patients with chronic fatigue syndrome: a randomized controlled trial. *J Intern Med, 279*(3), 268-282. doi: 10.1111/joim.12402

Wearden, A. J., Dowrick, C., Chew-Graham, C., Bentall, R. P., Morriss, R. K., Peters, S., . . . Dunn, G. (2010). Nurse led, home based self help treatment for patients in primary care with chronic fatigue syndrome: Randomised controlled trial. *BMJ (Online), 340*(7753), 959. doi: 10.1136/bmj.c1777

Wearden, A. J., Morriss, R. K., Mullis, R., Strickland, P. L., Pearson, D. J., Appleby, L., . . . Morris, J. A. (1998). Randomised, double-blind, placebo-controlled treatment trial of fluoxetine and graded exercise for chronic fatigue syndrome. *Br J Psychiatry, 172*, 485-490.

Wessely, S., Chalder, T., Hirsch, S., Wallace, P., & Wright, D. (1996). Psychological symptoms, somatic symptoms, and psychiatric disorder in chronic fatigue and chronic fatigue syndrome: a prospective study in the primary care setting. *Am J Psychiatry, 153*(8), 1050-1059. doi: 10.1176/ajp.153.8.1050

White, P. D., Goldsmith, K. A., Johnson, A. L., Potts, L., Walwyn, R., DeCesare, J. C., . . . Sharpe, M. (2011). Comparison of adaptive pacing therapy, cognitive behaviour therapy, graded exercise therapy, and specialist medical care for chronic fatigue syndrome (PACE): a randomised trial. *Lancet, 377*(9768), 823-836. doi: 10.1016/s0140-6736(11)60096-2

Wiborg, J. F., van Bussel, J., van Dijk, A., Bleijenberg, G., & Knoop, H. (2015). Randomised controlled trial of cognitive behaviour therapy delivered in groups of patients with chronic fatigue syndrome. *Psychother Psychosom, 84*(6), 368-376. doi: 10.1159/000438867

Windthorst, P., Mazurak, N., Kuske, M., Hipp, A., Giel, K. E., Enck, P., . . . Teufel, M. (2017). Heart rate variability biofeedback therapy and graded exercise training in management of chronic fatigue syndrome: An exploratory pilot study. *J Psychosom Res, 93*, 6-13. doi: 10.1016/j.jpsychores.2016.11.014

Zigmond, A. S., & Snaith, R. P. (1983). The hospital anxiety and depression scale. *Acta Psychiatr Scand, 67*(6), 361-370.

Service Improvement Project – The "My Wellbeing Toolkit"

Amy J Caswell

a.caswell@bath.ac.uk

Internal supervisor: Dr Emma Griffith, University of Bath

External supervisor: Dr Hanna van der Woude, B&NES Therapies Service

Temporary/maternity leave cover supervisors: Dr Chris Gillmore & Dr Claire Williamson

Word count: 4358

Date of report: 16th May 2018

Journal structure: Journal of Mental Health (See Appendix F for journal guidelines; all formatting is in line with journal requirements)

Abstract

Mind-maps are a graphical communication technique that has been found to enhance therapeutic work in substance misuse services. Despite their value in these settings, they have not been so frequently utilised in general mental health provision. To address this gap, a mind-map booklet, the "My Wellbeing Toolkit" was recently developed and introduced in an NHS Recovery Service. The current service improvement project aimed to explore uptake of the booklet and make recommendations for improvements to the booklet.

A three-stage sequential explanatory mixed methods study was used to explore the evaluation questions: the initial stage involved collecting data on the number of care coordinators who had used the booklet, from existing logs, the second stage involved collection of questionnaire data on usage patterns of the booklet, the third involved collection of qualitative data on experiences of using the booklet. Quantitative data was explored using descriptive statistics; qualitative data was analysed using thematic analysis.

Care coordinators identified that the booklet was useful for themselves and for clients, however uptake of the booklet was low. A number of barriers were identified: practical barriers, lack of confidence and clarity when using the booklet and a lack of client engagement. A series of recommendations were made to address these barriers and to improve the content of the booklet.

The project suggests that mind-map booklets have considerable value for mental health provision, however support needs to be provided to clinicians to facilitate their use. Future directions for research include exploring client experiences of mind-map based booklets.

Introduction

Mind-maps are a type of graphical communication technique (Dansereau & Simpson, 2009), developed for use in substance misuse counselling as a tool to enhance treatment effects, based on their effectiveness in educational settings (Dansereau, 2005).

In clinical and mental-health practice, mind-map booklets were pioneered by, and are regularly used in, substance misuse services, for example the "Routes to Recovery" booklet published by Public Health England (2013). The development of mind-maps, and the evaluation of their use in the field of substance misuse, has been led by the Texas Christian University (Bartholomew & Dansereau, 2008), the UK Birmingham Treatment Effectiveness Initiative (BTEI) (Day, 2009) and the International Treatment Effectiveness Project (ITEP), sponsored by the UK National Treatment Agency for Substance Abuse (Public Health England, 2013).

Mind-maps enhance therapy by organizing ideas and information spatially (Day, 2015). The theoretical basis for mind-mapping is that verbal language is constrained by its linear nature, which limits the ability to draw links between complex concepts and ideas; in contrast, visual information allows more complex clustering and linkage of ideas (Day, 2015). Drawing on this, mind-mapping grew out of an observation that typical counsellor note-taking was providing counsellors with visual information and representations, however these were not being accessed by clients, and therefore client understanding was being limited. Mind-maps were developed to provide a common visual experience between both counsellor and client (Day, 2015). During clinical sessions they enable sharing of ideas, clarify information and maintain focus on a given topic (Day, 2015).

Research has evidenced that mapping-enhanced counselling has benefits in increasing client motivation, engagement, participation, and retention in treatment (Dees, Dansereau, & Simpson, 1997; Joe, Dansereau, Pitre, & Simpson, 1997). Mind-maps have been found to promote more positive interactions with other clients and treatment staff, both in community-based and forensic settings (Pitre, Dansereau, Newbern, & Simpson, 1998). Outside of clinical sessions, mind-maps are suggested to enhance recall and confidence about material covered in sessions (e.g. Dansereau,

Joe, & Simpson, 1993; Dansereau, Dees, Greener, & Simpson, 1995; Knight, Dansereau, Joe, & Simpson, 1994; Newbern, Dansereau, Czuchry, & Simpson, 2005).

However, despite their usage and value in educational and substance misuse settings, mind-map booklets are not currently routinely utilised in mental health services. This lack of provision is striking, particularly in the current context of mental health provision, where low-intensity interventions are prioritised in the early stages of a person's care (NICE, 2011). To address this gap in service provision, a mind-map booklet (Avon and Wiltshire Mental Health Partnership NHS Trust, 2016) was recently developed and introduced for use by care coordinators in a Recovery Service in the South West of England, by a Clinical Psychologist working in adult mental health.

The current project

The current service improvement project aimed to explore uptake of the booklet and make recommendations, as necessary, for improvements to the booklet (Avon and Wiltshire Mental Health Partnership NHS Trust, 2016). To identify improvements, the project explored the clinician uptake and experience of the booklet, identified barriers to using the booklet and identified clinician opinions on how the booklet could be improved. Specifically, the project asked the following questions:

1. Have Recovery Service care coordinators been routinely using the booklet with clients?
2. Have care coordinators found the booklet helpful? If so, in what way?
3. What have been the barriers and facilitators to using the booklet? How can these be improved?
4. How do care coordinators think the booklet can be improved?

It was anticipated the project would improve the quality of the booklet and would improve the processes for use. Specifically, it was expected that identifying barriers and facilitators to use would enable the service to address these. It was also expected that understanding clinician's experiences of using the booklet and identifying their recommendations for improvement would improve the quality of the booklet.

Method

Design

A three-stage sequential explanatory mixed methods study (Cresswell, 2002) was used to explore the evaluation questions: the initial stage involved collecting data on the number of care coordinators who had used the booklet from existing logs, the second stage involved collection of questionnaire data on usage patterns of the booklet, the third involved collection of qualitative data on experiences of using the booklet. The project had relevant NHS trust service evaluation approval and University of Bath ethical approval (see Appendices G-I for relevant approvals)

Participants

Ten care coordinators in an NHS adult mental health Recovery Service completed the questionnaire. Seven care coordinators completed the focus groups (two focus groups were completed; two participants attended the first group, and five attended the second group), between March and October 2017.

Materials

Questionnaire pack. The questionnaire pack was developed for purpose and consisted of three sections described in Table 5 (see Appendix M for a copy of the questionnaire).

Focus Group. The focus group used semi-structured questions to provide an in-depth understanding of the experience of using the booklet. The focus group included questions regarding the benefits of using the booklet, the barriers and facilitators to use, and possible improvements (see Appendix N for a copy of the focus group schedule).

Table 5. Table detailing contents of the questionnaire.

Section	Contents
Section 1: Usage of the booklet and barriers/facilitators to use	Quantitative questions identified the usage of the booklet, including frequency, regularity and patterns of usage. Qualitative questions provided space to describe barriers and facilitators to use.
Section 2: Usefulness of the booklet	Quantitative questions identified the perceived benefits of the booklet, including whether participants would recommend it to colleagues and clients. All questions included space to provide further qualitative feedback.
Section 3: Improving the booklet	Consisted of qualitative space for participants to make recommendations about improvements to the booklet.

Procedure

First stage. The initial stage of the evaluation involved collecting data on the number of care coordinators who had collected booklets in the first six months after it was introduced to the service. This data was collected from existing sign out sheets kept with the booklets.

Second stage. The second stage of the evaluation involved collection of questionnaire data, completed approximately nine months after booklets were first introduced to the service.

Care coordinators were given information sheets and brief verbal information about the evaluation during team meetings. As recruitment to the questionnaires was initially lower than hoped, three blocks of recruitment were completed. Consenting care coordinators completed the anonymous questionnaire pack identifying their experiences of using the booklet. Participants either completed the questionnaire pack during a team meeting, or in their own time, returning them either to the lead investigator during team meetings or to a designated drop-off location in the service. Once they had participated, participants were given a brief written debrief where they

were thanked for participating. Questionnaires contained no identifying information, and consent forms were stored separately.

Third stage. The third stage of the evaluation was completion of two focus groups, nine and twelve months after the booklets were introduced to the service.

Care coordinators who had agreed to be contacted were invited to participate in the focus groups via email. Consenting care coordinators attended a focus group, lasting approximately 30-45 minutes. Once completed, participants received a brief verbal and written debrief and were thanked for participating. Focus groups were audio-recorded.

Analysis

Quantitative data from the questionnaire were explored using descriptive statistics.

Thematic analysis was completed on qualitative data, following the steps described by Braun and Clarke (2006). Qualitative data from the focus groups and questionnaires were combined into one dataset, following Braun and Clarke recommendations (Braun & Clarke, 2006, 2018); data were combined as the data from the questionnaires and focus groups addressed the same research questions and asked the same questions of participants. The two focus group interviews were transcribed from the audio-recordings. Preliminary immersion in the data involved repeated readings of all data, before initial codes were generated from the data, using NVivo version 10. Broader themes were then generated and reviewed before final themes and sub themes were identified.

Thematic analysis was used as this method is not tied to any particular theoretical perspective, allowing flexibility in its approach (Braun & Clarke, 2006). A deductive approach was used, driven by the research questions: interpretation was confined to considering the broader meaning and significance of the themes in relation to the evaluation questions. There was no attempt to uncover latent meaning within participants' language or discussion. Despite this attempt, it is acknowledged that there is always an unavoidable impact of the researcher, on the design, data collection and interpretation of the data. As such, double rating was not completed: the use of inter-rater reliability is underpinned by the assumption that there is an accurate reality

in the data that can be captured through coding, with no impact of the researcher, which is not the case in thematic analysis (see Braun & Clarke, 2006).

Results

Quantitative analysis

Usage patterns of the booklet. The log of the booklets indicated five care coordinators in the Recovery Service had signed out booklets to use.

Three of the ten participants who returned the questionnaire reported that they had used the booklet. Between these three participants, they had used the booklet with eight clients. One participant reported using the booklet "occasionally", another reported using at "approximately half the time" and the third did not provide a response.

When the booklets were not used with clients, six participants reported that they had not suggested using the booklet to their clients, one reported that they had suggested using it, but the client declined, two reported that the timing was not appropriate for their clients.

Usefulness of the booklet. The majority of questionnaire respondents had not used the booklet with clients. Of the available data, both participants who recorded using the booklet, reported that it was useful across all five dimensions (see Figure 7).

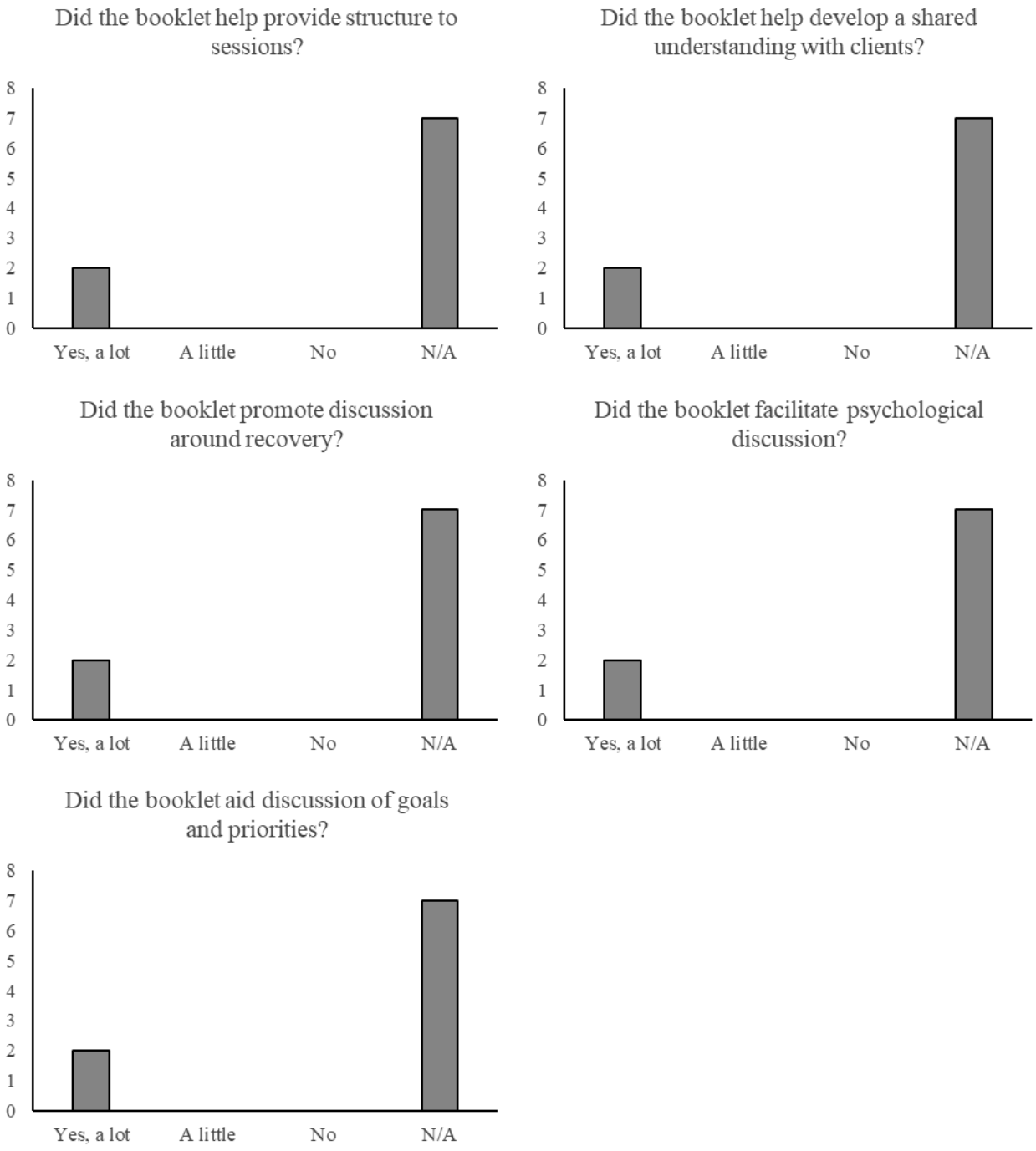


Figure 7. Graphs showing questionnaire responses.

N/A = participant indicated they had not used the booklet and were therefore unable to comment on its usefulness.

Qualitative analysis: thematic analysis

Three main overarching themes were identified from the thematic analysis: benefits of the booklet, barriers to use and suggestions for improvement to the booklet.

Benefits of the booklet. Participants in the focus groups described finding the booklets useful and a "great resource". Within the over-arching theme of 'benefits of the booklet', two subthemes were identified: 'benefit to the client' and 'benefit to the clinician'.

Benefit subtheme one: benefit to the client. Several care coordinators described that clients found the booklet helpful, and that it contained useful content, including coping strategies and understanding strengths and weaknesses:

"It's been useful... when they're [the client] reviewing it regularly… to learn some coping strategies and understand what their strengths and weaknesses are, it's really useful."

In addition, some care coordinators described that the booklet was helpful for complex clients, or those with particular needs, including those with a diagnosis of personality disorder.

"Some of the people that I've given this to with personality disorder have actually found it very helpful, because it's something that they can then have control over. It's something they can look at and work on, and it's very much their thing."

One care coordinator commented that, even when a client initially found it difficult to engage with support, with encouragement the booklet had been useful:

"Because one lady I've got really struggles with motivation, and with her, I have to really prompt her to get it out and have a look at it. But kind of keeping on at that time and again, it does seem that some of the information is sinking in a little bit, and she is a bit more motivated to look at it".

Benefit subtheme two: benefit to the clinicians. As well as benefiting clients, care coordinators felt that the booklet benefited themselves

They felt that, if used correctly, the booklet could support them to get to know a client better, and to learn about their background, goals and insight:

"I did this more as an ability to try to get to know them … and getting to know their insight into their life"

They also thought that the booklet could support the care a client received from the service, in particular care planning. They also thought that it would have value for other professionals, particularly with regards to transfer of care or hospitalisations:

"It's also a nice thing as part of the discharge, actually, especially writing a letter to the GP, or if primary care liaison picks up, at another stage, that this tool has been used, and potentially, there's a sharing possibility."

Barriers to using the booklet. A theme of barriers to using the booklet was identified, with a number of care coordinators noting that they had not used the booklets. Within the theme of barriers to use, three subthemes were identified: practical barriers, lack of clarity and confidence using the booklet, and lack of client engagement,

Barriers subtheme one: Practical barriers. A number of care coordinators were not aware of the booklet or did not know where to collect the booklets from, or knew how many they could have:

"I … was unaware of the booklets"

"Partly, I think, there was a sense that we were perhaps allowed one"

"Sometimes, it's kind of like, "Where are they kept?" or running around to try to find them."

Barriers subtheme two: Lack of clarity and confidence over the application of the booklet. A key subtheme that came up was that a lack of clarity over the purpose and application of the booklet was experienced as a barrier to using it.

"I suppose, yes, there is an element… about the training behind it, like what is the purpose of it, I think, maybe, needs to be clearer … "When do I use it? Why am I using it? What's the purpose of these?"

"I think it's a very, very difficult one all round, if I'm being honest, because it is about when do you pick it up? Why do you pick it up? When do you review it? How is the service user using it?"

Care coordinators spoke about a lack of confidence in terms of knowing whether they should be completing it with clients, or if clients were meant to complete it independently:

"The title "My wellbeing booklet" ... makes some [service users] feel it is for them to complete by themselves"

Some participants explained that this lack of understanding of the purpose of the booklet was compounded by other work-based pressures, which meant they prioritised mandatory work, and did not take up opportunities to use or explore the booklet:

"[A barrier is] lack of time and having already commenced other pieces of work with service users whom I have been allocated for a while"

"I think it's probably because it's, sadly just another thing we have to pick up. It's not like a mandatory thing; it's more like something that's there that's optional to use. You just sometimes just don't opt into having another thing to use."

Barriers subtheme three: Lack of client engagement. Care coordinators described that some clients did not want to use the booklet, and that if a client was not engaged they did not bring the booklet to sessions:

"Yes, I've been clear about getting them to bring it back, and that we could use it in a session. But yes, when they've not brought it back, and just not knowing, really, where we were going with it, at that point."

"The [booklets] I've given out, they then don't bring it back."

Improvements to the booklet. Two subthemes were identified within the theme of improvements for the booklet: suggestions for additional content in the booklet, and suggestions for improving accessibility and guidelines about using the booklet.

Care coordinators liked the layout and design of the booklet, and thought it was user friendly. They liked that it did not contain jargon, and that it could be photocopied for repeated use.

Suggestions for improvement one: Additional content. Care coordinators suggested the following additions to the booklet:

1. Additional information about online/email/text support services, for self-harm and mental health difficulties:
   "[Information on] online support for self-harm. I know that some people have had difficulty with phone-in services There are some quite good online- …. I'm just wondering if they're in here for people that aren't able to phone and make that contact."

   "You've got a couple of apps, but …I know there are some support services where you can have email support or text support instead of phoning them, if you need to."
2. Information on the role of attachment in mental health difficulties:
   "For me, something on attachment would be helpful, because I think that often underlies those difficulties we work with… maybe thinking about their own styles and exploring curiosity around that."
3. Information on the experience of hearing voices
   "A section on psychosis: hearing voices, delusions, and that sort of thing… At Recovery Team level, it's fairly common. Yes, at this level of service, I think it would be really important."
4. A page to record contact details of professionals involved in clients' care

There were two suggestions that the format of the booklet could be improved. It was suggested that the booklet could be developed into an electronic app or pocket-sized version.

There was also a suggestion that modifying the booklet to allow progress and change to be logged would be useful, and that this might be facilitated through changing the binding of the booklet to allow pages to be slotted in:

There was one suggestion that the wording of a particular page, the "discovery page" could be changed, otherwise care coordinators thought that nothing should be removed from the booklet.

Suggestions for improvement two: accessibility and guidelines about using the booklet. It was recommended that the booklet will be most helpful at initial entry into the service and at discharge, and that use of it should be led by the client, who should be allowed to opt in or out of the booklet.

To ensure the booklet is accessible, it was suggested that the booklet should be left in the admin office or put with new referral packs.

It was suggested that a training session could be scheduled, using an example case to demonstrate use of the booklet.

Outcomes: feedback, recommendations and next steps

It was fed back to the service during a meeting with the booklet developer, that care coordinators felt that the booklet had several benefits for both clients and care coordinators, but that uptake of the booklet had been low. The barriers to using the booklet were discussed, as well as the recommended improvements of how to address these. The recommendations for addressing barriers to use are summarised in Table 6.

Table 6. Table listing recommendations for addressing barriers to use of the booklet.

Barriers to use:	**Recommendations:**
Practical barriers	Service should consider keeping the booklets in an accessible location that care coordinators are aware of. Service should consider providing the booklets to care coordinators when they receive a new referral. Service should consider regularly reminding care coordinators of booklets, to ensure that use continues.
The lack of clarity and confidence over the application of the booklet	Service should consider holding training sessions covering: 1. Information on the intended purpose of the booklet 2. Information and discussion of how best to use the booklet with clients (for example at intake and discharge from the service) 3. Information and discussion on how to use the booklet with more complex clients, and how to consider who the booklet might be appropriate for Service should consider providing regular drop-in sessions for clinicians to access supervision and support on how to use the booklet, and troubleshooting.
Lack of client engagement	Service should recognise that the booklet won't be appropriate for all clients, and clients should have the option to decline to use the booklet. Service should consider the above recommendations to address practical barriers and the lack of confidence and clarity as a means of improving clinician engagement with the

	booklet, thereby improving the motivation to use the booklet during sessions. Service should consider gathering client feedback on the booklet in the form of a future service improvement project or review, to explore whether the booklet is perceived as useful by clients, and when in their support it is useful

The following recommendations were also made for a possible second edition of the booklet:

1. To consider including:
    a. Additional content on attachment
    b. Additional content on experiences of hearing voices
    c. Details of email and text support services on the page of services, as well as talking therapies
    d. A front page with space to record contact details of involved clinicians
2. To consider changing the format of the booklet to allow insertion of extra sheets
3. To consider development of an electronic app version of the booklet

Feedback from the service

The service fed back that the project had been very useful and had furthered the use of the booklet. They intended to take the recommendations forward, particularly those to address the barriers to use, and hoped to introduce the booklet to new teams in the Trust.

Next steps and further research

With regards to next steps, the service intended to meet with the Trust Clinical Commissioning Group to feedback clinicians' experiences of using the booklet, make a case for introducing the booklet to new teams within the Trust and suggest recommendations for improvement. To facilitate this, a one-page summary of the service improvement project was drawn up and provided to the service (see Appendix O).

It was recommended that a future evaluation should be considered to identify whether the recommendations of the current project have improved usage and uptake of the

booklet. It was also recommended that the service should consider gathering client feedback on the booklet in a future service improvement project, to ensure the booklet is perceived as useful by clients. It is possible that identifying if clients find the booklet helpful, would improve uptake of the booklet by clinicians by addressing the perceived barrier of lack of client engagement. These projects would provide further evidence of the value of mapping enhanced mental health support.

Discussion and implications

The current project aimed to explore uptake of the "My Wellbeing Toolkit", a mind-map based booklet recently introduced to the Recovery Team and recommend improvements to the booklet.

The project identified that usage of the booklet had been low within the Recovery Service, and that clinicians had not been routinely using the booklet. However, despite the low uptake, clinicians identified a number of benefits of the booklet, reporting the booklet was useful for both clinicians and clients. They thought the booklet was user-friendly, provided a platform for them to get to know their clients and also aided with information sharing between professionals. Participating care coordinators thought the booklet contained useful content for clients and that it was suitable for a range of psychological difficulties. Three primary barriers to use were identified, that may have contributed to the low uptake of booklet: practical barriers, lack of clarity and confidence over the application of the booklet. and lack of client engagement. Participants made a series of recommendations for improvements. Based on these findings, recommendations were made to the service to address barriers to use and for improvements to the booklet content. The findings were well received and accepted by the service, who intended to take the recommendations forward.

The project suggests mind-map based booklets such as the "My Wellbeing Toolkit" have value for mental health provision. While these booklets have been previously used in substance misuse services (Public Health England, 2013) they have not been extensively used in general mental health recovery services. Previous research has identified mind-map based tools have a number of benefits (Dansereau et al., 1993; Dees et al., 1997; Joe et al., 1997; Pitre et al., 1998). The current project found that in mental health settings mind-map booklets have considerable value for both clinicians and clients. However, the project also identified there may be service-level barriers to

implementing booklets which need to be considered if booklets are to be successfully introduced into services.

Strengths, limitations and further considerations

The project has a number of strengths. The use of qualitative analysis means it was possible to gather a rich understanding of experiences of using the booklet, to make recommendations of how it could be improved. The project met its objectives and is the first to provide a specific evaluation of the use of mind-map based booklets in non-substance misuse secondary care mental health services. There are limitations that should be considered. It is possible that the record of the number of clinicians who had used the booklet may have underestimated their use, as clinicians might have taken booklets without signing them out and as participation in the current project was optional for care coordinators. Despite multiple attempts to recruit to the questionnaire, inviting all care coordinators within the team to participate on a number of occasions, only ten care coordinators did so and only two could give data on their usage patterns. This meant that the sample size was relatively small and may not have provided an accurate account of usage within the service. Making the questionnaire compulsory would have raised significant ethical considerations, and therefore we were reliant on participants volunteering. There are also limitations to using a questionnaire that was designed for purpose, as it does not have any reliability or validity statistics, however although it does allow tailoring to the specific project aims. An additional limitation is that as the evaluation focused solely on the clinician experiences of the booklet, it does not give insight into client experiences of the booklet.

With regards to other considerations, it is important to note that the focus groups consisted of a mix of clinicians who had and had not used the booklet. While this reflected the limited uptake of the booklet, it is possible that this affected the findings as a number of participants had no experience of using the booklets, and therefore will not have had direct experience of any benefits or disadvantages of use. However, importantly, these clinicians were able to provide comprehensive information on the barriers they experienced to use. Had uptake of the booklet been greater, with a larger available participant pool, it may have been more appropriate to complete separate focus groups with participants who had and had not used the booklets.

It can also be questioned whether the focus group schedule or analysis method were most appropriate for this project. Considering the high overlap between the questions asked in the focus groups and questionnaires and the themes generated, it could be suggested that the themes identified are less reflective of general themes and instead more descriptive (Vaismoradi, Turunen, & Bondas, 2013). It is therefore possible that content analysis might have been a more appropriate analytic approach for the data (Vaismoradi, Turunen, & Bondas, 2013). Furthermore, the focus groups focused exclusively on the particular toolkit and questions were specific and service focused. It is therefore possible that the themes identified cannot be generalised beyond the scope of the individual "My Wellbeing Toolkit" resource. To increase generalisability, it may have been more appropriate to complete a focus group or interviews on broader ideas and views of working with clients using mind-map based tools, to provide a richer understanding of these types of resources, as opposed to this particular booklet. This could then be analysed with IPA on a smaller sample of participants.

Summary and conclusions

The current project aimed to make recommendations for improvement for the "My Wellbeing Toolkit", a mind-map based booklet recently introduced to the Recovery Service. The project identified a number of benefits of using the booklet, for both clinicians and clients, however uptake of the booklet was low. Three main barriers to using the booklet were identified. Recommendations of how to address these barriers were made, in addition to recommendations for additional content that could be included in a future edition of the booklet.

In conclusion, the current project suggests that map-based booklets have value for mental health services, however thought needs to be given as to how to ensure that they are used within teams. The findings suggest that there may be simple and manageable ways to reduce barriers to uptake, and that, when used appropriately, both clinicians and clients can benefit from mind-maps in mental health services.

References

Avon and Wiltshire Mental Health Partnership NHS Trust. (2016). *My Well-being Toolkit*.

Bartholomew, N. G., & Dansereau, D. F. (2008). Mapping-Enhanced Counseling: An Introduction. In T. I. o. B. R. a. TCU (Ed.).

Braun, V., & Clarke, V. (2006). Using thematic analysis in psychology. *Qualitative Research in Psychology, 3*(2), 77-101.

Braun, V., & Clarke, V. (2018). Thematic analysis. Retrieved 1st April, 2018

Cresswell, J. W. (2002). *Research Design: Qualitative, Quantitative, and Mixed Methods Approaches* (2nd Edition ed.): SAGE Publications.

Dansereau, D., Joe, G., & Simpson, D. D. (1993). Node-link mapping: A visual representation strategy for enhancing drug abuse counseling. *J. Couns. Psychol., 40*(4), 385-395.

Dansereau, D. F. (2005). Node-link mapping principles for visualizing knowledge and information. In S. O. Tergan & T. Keller (Eds.), *Knowledge and Information Visualization* (pp. 61-81): Springer-Verlag.

Dansereau, D. F., Dees, S. M., Greener, J. M., & Simpson, D. D. (1995). Node–Link Mapping and the Evaluation of Drug Abuse Counseling Sessions. *Psychology of Addictive Behaviors, 9*(3), 195-203. doi: 10.1037/0893-164X.9.3.195

Dansereau, D. F., & Simpson, D. D. (2009). A picture is worth a thousand words: The case for graphic representations. *Professional Psychology: Research and Practice, 40*(1), 104-110. doi: 10.1037/a0011827

Day, E. (2009). The Birmingham Treatment Effectiveness Initiative (BTEI) An Introductory Guide.

Day, E. (2015). What Is… Node-link Mapping? Retrieved 2nd Feb 2018

Dees, S. M., Dansereau, D. F., & Simpson, D. D. (1997). Mapping-enhanced drug abuse counseling: urinalysis results in the first year of methadone treatment. *J Subst Abuse Treat, 14*(1), 45-54.

Joe, G. W., Dansereau, D. F., Pitre, U., & Simpson, D. D. (1997). Effectiveness of node-link mapping enhanced counseling for opiate addicts: a 12-month posttreatment follow-up. *J Nerv Ment Dis, 185*(5), 306-313.

Knight, D. K., Dansereau, D. F., Joe, G. W., & Simpson, D. D. (1994). The role of node-link mapping in individual and group counseling. *American Journal of Drug and Alcohol Abuse, 20*(4), 517-527. doi: 10.3109/00952999409109187

Newbern, D., Dansereau, D., Czuchry, M., & Simpson, D. (2005). Node-Link Mapping in Individual Counseling: Treatment Impact on Clients with ADHD-Related Behaviors. *Journal of Psychoactive Drugs, 37*(1), 93-103. doi: 10.1080/02791072.2005.10399752

NICE. (2011). Common mental health problems: identification and pathways to care: Clinical guideline [CG123].

Pitre, U., Dansereau, D. F., Newbern, D., & Simpson, D. D. (1998). Residential drug abuse treatment for probationers. Use of node-link mapping to enhance participation and progress. *J Subst Abuse Treat, 15*(6), 535-543.

Public Health England. (2013). *Routes to Recovery*.

Main Research Project - HPV-related shame, stigma, depression and anxiety in women with cervical cancer

Amy J Caswell

a.caswell@bath.ac.uk

Internal supervisors: Dr Cara Davis & Dr Megan Wilkinson-Tough

External supervisor: Dr Samantha Cole

Word count: 4392

Date of report: 16th May 2018

Journal structure: Psycho-Oncology (See Appendix P for journal guidelines; all formatting is in line with journal recommendations)

Note: Journal requires numbered references – these have been changed to APA 6th formatting for the purposes of this portfolio, to meet university requirements and to maintain consistency throughout the portfolio.

Data from this project was presented as an open paper at the 2018 BABCP conference

Abstract

Cervical cancer patients are at particular risk of experiencing psychological distress and mental health difficulties. The current study investigated whether this is associated with knowledge of the sexually-transmitted nature of HPV, exploring HPV-related shame, anxiety and low mood in women with cervical cancer.

110 women with cervical cancer completed a repeated measures study, during which they read information that HPV is (1) considered to be a sexually-transmitted virus and (2) very common. Participants completed measures of shame, mood and anxiety after each level of information.

The results indicated that information that HPV is sexually-transmitted is associated with experiences of shame. Increased shame was associated with depression, low mood, anxiety and poor wellbeing. Women with a history of depression and anxiety were at particular risk for experiencing high levels of shame.

The results indicate that women with cervical cancer experience high levels of shame related to HPV information. This has implications for how to support patients who are at risk of experiencing high levels of shame, particularly around HPV-information provision, identifying at-risk patients, and the psychological support of patients.

Key words

Anxiety; Cancer; Cervical Cancer; Depression; Human Papilloma Virus; HPV; Oncology; Psychology; Shame;

Introduction

Background

There are over 3000 new cases of cervical cancer in the UK each year. Cervical cancer is considered a "preventable" cancer; close to 100% of cases are associated with high-risk strains of a common infection, Human Papilloma Virus (HPV), transmitted through intimate skin-to-skin contact during sex (Cancer Research UK, 2016). HPV is very common, and it is estimated that at least 80% of people will contract the virus at some point in their life.

Research has indicated that cervical patients are at particular risk of experiencing anxiety, depression and other mental health difficulties, over and above the general population (Bradley, Rose, Lutgendorf, Costanzo, & Anderson, 2006) and patients with other gynaecological cancers (Bradley et al., 2006). Factors that have been implicated in this risk for psychological distress include the related constructs of shame and stigma. It is known that HPV diagnosis is associated with shame, anxiety and distress (Kahn et al., 2007; Maissi et al., 2004). A recent survey found that 20% of women associated gynaecological cancers with sexual promiscuity and close to 40% of women felt that gynaecological cancers are particularly stigmatised types of cancer. In the same survey, over one third of women thought that reducing shame and stigma around gynaecological health and sex would enable them to talk more openly about such health issues (The Eve Appeal, 2015).

Shame is a complex, multi-faceted experience that can be both externally focused (i.e. focusing on what others think about the self, referred to as 'external shame', e.g. "others think I am a bad person") and internally focused (i.e. focusing on what the person thinks about themselves, referred to as 'internal shame', e.g. "I am a bad person") (Gilbert, 2006). As these two types of shame are considered closely related, they are often collectively be referred to as shame, with much literature failing to differentiate between the two (Gilbert, 2006). Shame is typically associated with a strong emotional response, for example anxiety, anger and disgust (Gilbert, 2006). Shame is considered to be strongly related to cultural values (Gilbert, 2006), which has particular implications for understanding experiences of shame in women with cervical cancer. As previously described, cervical cancer is associated with HPV, a sexually-transmitted virus (an STI), and the risk of HPV increases with number of

partners. In Western society, 'permissive' values in sexual relationships, i.e. having multiple or casual sexual partners, remains culturally stigmatised (e.g. Vrangalova, Bukberg, & Rieger, 2014) and there is evidence that this stigma extends directly to cervical cancer, with patients in a vignette being rated by others as more "dirty", "dishonest" and "unwise", and triggering feelings of moral disgust, when HPV is specified as the cause (Shepherd & Gerend, 2013).

Research has found that this cultural stigma may be associated with individuals' experiences of HPV-related shame. A quasi-experimental study found that non-clinical participants experienced higher levels of shame and stigma when asked to imagine their reaction to a hypothetical HPV diagnosis, when told HPV is sexually-transmitted, compared to reduced shame when told HPV is very common (Waller, Marlow, & Wardle, 2007). Further qualitative research with HPV positive women, who do not have a diagnosis of cervical cancer, found that testing positive for HPV was associated with feelings of stigma, primarily linked to the sexually-transmitted nature of the virus, and its association with cervical cancer (McCaffery, Waller, Nazroo, & Wardle, 2006). The same research indicated that knowledge of the high prevalence of HPV might reduce experiences of shame around their diagnosis (McCaffery et al., 2006).

In addition to feelings of stigma, McCaffery and colleagues (2006) found HPV positive women also experienced higher levels of anxiety and stress. This suggests that HPV-related shame may be associated with poorer wellbeing. While there is no research specific to cervical cancer, shame and stigma are known to be related to poorer quality of life and higher psychological distress in lung cancer (Chambers et al., 2012) and there is evidence that shame is particularly associated with depression in cancer more generally (Kim, Thibodeau, & Jorgensen, 2011).

The current study

Despite the above research, there has previously been no examination of how women with cervical cancer experience information about HPV. It is not known whether knowledge that HPV is sexually-transmitted is associated with internal or external shame or poor mental wellbeing, or whether information that HPV is very common normalises the experience of having HPV and reduces internal or external shame. It

is also not known whether internal or external shame is associated with an increased risk of psychological distress and mental health difficulties in patients.

The current study aimed to address these questions by presenting information about HPV and measuring psychological experiences of participants. The research questions, and related hypotheses, are presented in Table 7.

Table 7. Table presenting study research questions and related hypotheses

Research question	**Related hypotheses**
Is shame in cervical cancer associated with knowledge that HPV is sexually-transmitted?	Pre-existing knowledge that HPV is sexually-transmitted would be associated with higher baseline levels of shame. Activation of knowledge that HPV is sexually-transmitted would be associated with increased shame.
Does information that HPV is very common reduce experiences of shame in women with cervical cancer?	Pre-existing knowledge that HPV is very common would be associated with lower levels of baseline shame. Activation of knowledge that HPV is very common would be associated with reductions in state shame.
Is shame associated with increased depression and anxiety in women with cervical cancer?	Activation of knowledge that HPV is sexually-transmitted would be associated with reductions in mood and wellbeing and increases in levels of anxiety. Activation of knowledge that HPV is very common would be associated with an increase in mood and wellbeing and reduction in anxiety. Higher levels of shame at baseline would be associated with higher depression and anxiety at baseline. History of depression and anxiety would be associated with higher levels of shame at baseline.

Note - In all hypotheses "shame" refers to internal and external shame, both of which were measured separately. There was no specific hypothesis as to whether internal or external shame differed within any of the above research questions.

It was anticipated that findings could help clinicians to better understand the emotional experiences of patients, not only helping inform how they provide information, but also how they support them through the information, diagnosis and treatment process more generally.

Method

Participants

One hundred and ten women with cervical cancer completed the current study. Participants were recruited through online sources, including the Jo's Cervical Cancer Trust charity website, social media platforms, including Facebook and Instagram, other women's health charity and support websites, and through two NHS gynaecological-cancer centres.

Participants were required to be women fluent in English, over the age of 25, with a past or current diagnosis of cervical cancer. Women concerned that they have cervical cancer but with no confirmed diagnosis were not eligible to participate.

An a priori power analysis, using G-Power version 3.1.5, indicated that 110 participants would be required to have 80% power for detecting a small-sized effect for the primary hypothesis, with the traditional .05 criterion of statistical significance.

Design

The study used a repeated measures design adapted from Waller, Marlow and Wardle's design (Waller et al., 2007).

The study had ethical approval from the Health Research Authority (IRAS 217863; REC reference 17/WA/0106) and the University of Bath (approval code 17-133). See Appendices Q-S for copies of ethical approval notifications.

Procedure

The study was completed online via Qualtrics survey software. Participants provided informed consent at the beginning and end of the study, self-confirming that they met inclusion criteria (see Appendix T & U)

Participants first completed a demographic questionnaire, cancer demographic questionnaire, measure of lifetime depression and anxiety, the Hospital Anxiety and Depression Scale, the Warwick-Edinburgh Mental Wellbeing Scale, the State Shame and Guilt Scale (SSGS) and the Modified State Shame and Guilt Scale (MSSGS). They then completed a multiple-choice quiz identifying their baseline knowledge of HPV, including transmission and prevalence of HPV.

Participants were then presented with three different levels of information about HPV. The first level of information ("general" information) explained that cervical cancer is associated with HPV. The second and third levels of information stated that HPV is sexually-transmitted ("STI" information), and that the virus is extremely common ("common" information). See "materials" for details of the different levels of information. Presentation of "STI" and "common" information was counter-balanced, with half of the participants receiving "STI" information first and half receiving the "common" information first, achieved via Qualtrics randomiser.

After each level of information, participants repeated the SSGS, MSSGS and brief mood ratings. To ensure they were linked with the information, questions were presented directly referencing the information the participant just read, for example "When I think about the information XXX, I feel XXX".

Finally, participants completed a manipulation check in the form of a brief version of the multiple-choice quiz. This was to allow the authors to check that all participants had correctly understood the HPV information.

Once participants had completed the protocol they were debriefed. Participants were not directly reimbursed for their participation, instead a charity donation of £1 was made for each participant.

Materials

HPV information

"General" information consisted of the following statement:

"A virus called human papillomavirus (HPV) is now known to be involved in the development of cervical cancer (cancer of the cervix or neck of the womb).

For most women, the immune system clears the virus and there are no health problems associated with it.

However, if infection persists, it can lead to abnormalities in the cells of the cervix.

These cells then have an increased risk of becoming cancerous."

"STI" information consisted of the statement:

"HPV is transmitted through intimate skin-to-skin contact during sex. It is sexually-transmitted."

"Common" information consisted of the statement:

"HPV is very common. It is estimated that currently around 80% of people will be infected with HPV at some point in their lives. That means that of every 5 people you know, approximately 4 will have had the virus."

Demographic questionnaire. The demographic questionnaire asked for general information, including the participant's age, country of residence, ethnicity, education, relationship status, and history of depression and anxiety. History of depression and anxiety was recorded using the following two brief items, adapted from the Structured Clinical Interview for DSM-IV (First, Spitzer, Gibbon, & Williams, 2002):

1. Have you ever had a period of time during your life when you were feeling depressed or down most of the day, nearly every day? (a) Yes, once (b) Yes, more than once (c) No
2. Have you ever had a period of time during your life when you were feeling very anxious or worried most of the day, nearly every day? (a) Yes, once (b) Yes, more than once (c) No

Cancer demographic questionnaire. The cancer demographic questionnaire asked for cancer specific information, including type and stage of cervical cancer, and treatments.

Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983). The HADS is a 14-item questionnaire measuring current anxiety and depression. The primary outcome variables are total scores for anxiety and depression; scores range

from 0-21, with scores of 8 or more indicating clinical caseness (Bjelland, Dahl, Haug, & Neckelmann, 2002).

Warwick-Edinburgh Mental Well-Being Scale (WEMWBS; NHS Health Scotland, 2006). The WEMWBS is a 14-item questionnaire measuring psychological well-being. The primary outcome variable is wellbeing; scores can range from 15-70, with higher scores indicating better wellbeing

State Shame and Guilt scale (SSGS; Marschall, Sanftner, & Tangney, 1994). The SSGS is a 15-item questionnaire measuring internal shame, guilt and positive affect. For the purposes of the current study, the primary outcome variable is internal shame; guilt and positive affect are not relevant to the current study and so will not be discussed.

Modified State Shame and Guilt scale (MSSGS; adapted from Marschall et al., 1994). To index external shame, the 15-item SSGS was modified to identify how the participant believes other people feel about them, rather than how the participant feels about themselves (i.e. external shame, rather than internal). The primary outcome variable is external shame.

Multiple-choice quiz (MCQ). The MCQ consisted of 9 multiple-choice items, developed by the authors, to establish participants' baseline knowledge about cervical cancer and HPV. Six items were included as fillers, three items identified whether participants were aware cervical cancer is associated with HPV and that HPV is sexually-transmitted, and whether they had an accurate understanding of the prevalence of HPV.

Brief Multiple-choice quiz (brief MCQ). The brief MCQ was a 3-item version of the MCQ, in which the six filler items were removed, and three items identified whether participants were aware cervical cancer is associated with HPV and that HPV is sexually-transmitted, and whether they had an accurate understanding of the prevalence of HPV.

Brief mood ratings. Brief mood ratings of low mood, anxiety and wellbeing were recorded using 0-10 scales to identify participants' current mood, developed by the authors.

Please see Appendices W-Y for copies of all non-copyrighted materials.

Statistical analysis

All data were explored using IBM SPSS Statistics, version 22. Answers on the Brief MCQ were first checked, to exclude any participants who had not correctly understood the HPV information by the end of the study.

Demographics. Participant general and cancer-specific demographics were explored using descriptive statistics.

Knowledge of HPV information. Correct answers on the MCQ at baseline were explored using descriptive statistics, to identify how many participants had pre-existing knowledge that cervical cancer is associated with HPV, and that HPV is considered a sexually-transmitted infection. Descriptive statistics were also used to explore participants' estimates of the prevalence of HPV in the general population.

Association between HPV knowledge and feelings of shame. The association between HPV knowledge and feelings of shame was explored both at baseline (i.e. pre-existing knowledge) and following activation of knowledge during the study.

Pearson's correlations were performed to explore whether there was a relationship between baseline estimates of HPV prevalence and internal and external shame. One further comparison was planned between those correctly identifying HPV as sexually-transmitted and those who did not know this fact at baseline on the MCQ. However, as all participants were correct, this was not possible.

To explore the effects of activated information on levels of internal and external shame, repeated measures ANOVAs (baseline vs following "STI" information vs following "common" information) were performed; Bonferroni corrected post-hoc tests were performed to identify significant differences between the three time-points.

Association between shame and depression, anxiety and wellbeing. Pearson's correlation coefficients were run to explore whether there was a significant relationship between baseline internal and external shame on the SSGS and MSSGS, and experiences of depression and anxiety (as recorded on the HADS) and wellbeing (on the WEMBWS). Women who recorded that they had experienced multiple episodes of depression and anxiety in their lifetime were compared to those with no history, or a single episode, on measures of baseline shame using one-way ANOVA.

Paired samples t-tests were used to compare mood ratings following "STI" and "common" information (these ratings were not recorded at baseline).

Results

Participant demographics

Participant demographics are presented in Table 8.

Baseline cervical cancer knowledge

In the baseline multiple-choice quiz, all participants (100%) correctly identified that cervical cancer is associated with HPV, and that HPV is primarily transmitted through intimate skin-to-skin contact, particularly during sex. Participants gave a mean estimate that 70.61% (SD 18.98; median 76%; range 9-100) of the population contract HPV at some point in their lifetime, where the correct estimate is approximately 80%.

Association between HPV knowledge and feelings of shame

Existing knowledge and experiences of shame. As all participants were aware that cervical cancer is associated with HPV, it was not possible to compare levels of shame between women who did and did not know.

There was not a significant correlation between estimates of HPV prevalence and internal ($r(109)=-.006$, $p=.953$) or external ($r(106)=-.013$, $p=.897$) shame.

Table 8. Participant demographic information

	Mean (s.d.)
Age (years)	40.62 (9.98)
HADS Depression	6.03 (3.92)
HADS Anxiety	9.53 (4.36)
WEMWBS Wellbeing	43.87 (11.50)
SSGS Internal shame	9.54 (4.62)
MSSGS External shame	8.42 (4.29)
	N (%)
History of depression	
Yes, once	22 (20%)
Yes, multiple	60 (63.6%)
No	17 (15.5%)
History of anxiety	
Yes, once	13 (11.8%)
Yes, multiple	83 (75.5%)
No	14 (12.7%)
Education	
GCSE (or equivalent)	17 (15.5%)
A level (or equivalent)	23 (20.9%)
Undergraduate degree	38 (34.5%)
Postgraduate degree	23 (20.9%)
Prefer not to answer	9 (8.2%)
Country	
UK	43 (39.1%)
USA	50 (45.5%)
Other	17 (15.5%)
Ethnicity	
White	104 (94.5%)
Mixed/multiple ethnic groups	3 (2.7%)
Other	3 (2.7%)
Relationship status	
Single	19 (17.3%)
Committed or exclusive relationship	12 (10.9%)
Married or domestic partnership	70 (63.6%)
Widowed	3 (2.7%)
Divorced or separated	6 (5.5%)
Cervical cancer diagnosis	
Squamous cell cancer	43 (39.1%)
Adenocarcinoma	36 (32.7))
Other	31 (28.2%)
Cervical cancer stage	
In remission	40 (45.5%)

Activated knowledge and experiences of shame. There was a significant effect of type of information on levels of internal shame on the SSGS, $F(1.785, 187.414)=14.320$, $p<.001$; df huynh-feldt corrected. Shame was significantly higher after reading information that HPV is sexually-transmitted (M 12.19, SD 7.38) compared to baseline (M 9.54, SD 4.71), $p<.001$; there was no difference between levels of shame after reading information that HPV is very common (M10.03, SD 6.38) compared to baseline shame, $p=1.00$; shame was significantly lower after reading "common" information when compared to "STI" information, $p<.001$. See Figure 8a.

Figure 8a

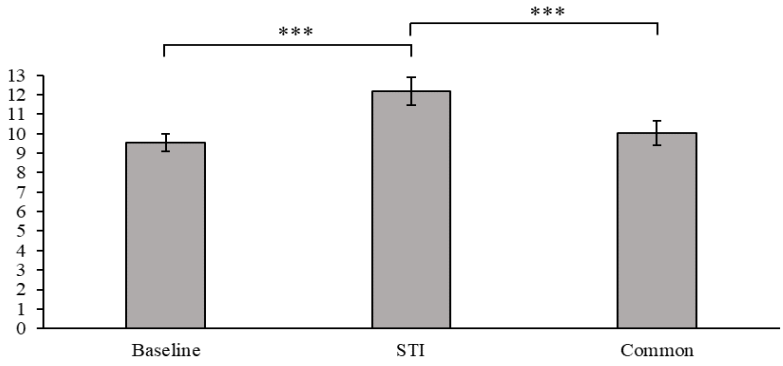


Figure 8b

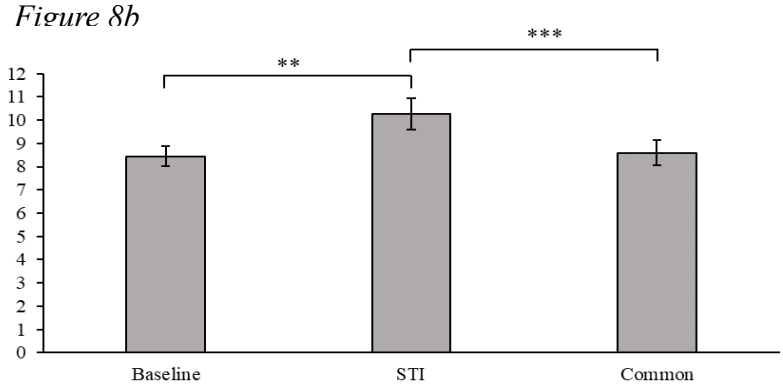


*Figure 8. Bar graph showing mean internal (Figure 1a) and external (Figure 1b) shame scores, as recorded on the modified SSGS, at baseline and following "STI" and "common" information. **p<.01; ***p<.001.*

Similarly, there was a significant effect of information on levels of external shame on the modified SSGS, $F(1.795, 181.282)=9.452$, $p<.001$; df huynh-feldt corrected). Shame was significantly higher after reading information that HPV is sexually-transmitted (M 10.26, SD 6.94) compared to baseline (M 8.44, SD 4.37), $p=.003$; there

was no difference between levels of shame after reading information that HPV is very common (M 8.60, SD 5.55) compared to baseline shame, p=1.00; shame was significantly lower after reading "common" information when compared to "STI" information, p<.001. See Figure 8b.

Association between shame and depression, anxiety and wellbeing

Internal and external shame were associated with higher levels of depression and anxiety and were also associated with poorer wellbeing. See Table 9 for full correlation matrix.

Table 9. Correlation matrix of baseline depression, anxiety wellbeing and internal and external shame

		HADS anxiety	HADS depression	WEMWBS wellbeing	SSGS Internal shame	MSSGS External shame
HADS anxiety	Pearson's *r*	1				
	N	109				
HADS depression	Pearson's *r*	.654***	1			
	N	109	110			
WEMWBS wellbeing	Pearson's *r*	-.718***	-.817***	1		
	N	104	105	105		
SSGS Internal shame	Pearson's *r*	.619***	.636***	-.722***	1	
	N	109	110	105	110	
MSSGS External shame	Pearson's *r*	.472***	.484***	-.609***	.817***	1
	N	106	107	102	107	107

*HADS=Hospital Anxiety and Depression Inventory; WEMWBS = Warwick Edinburgh Mental Wellbeing Scale; SSGS = State Shame and Guilt Scale; MSSGS = modified State Shame and Guilt Scale. ***p<.001*

History of depression was associated with differences in baseline levels of internal [F(2,106)=10.967, p<.001] and external [F(2,103)=7.082, p=.001] shame. Post hoc tests indicated that women with multiple episodes of depression had significantly higher internal shame (M 10.93, SD 4.85) than those with a single episode of depression (M 7.82, SD 3.62), p=.011, and those with no history of depression (M 6.12, SD 1.36), p<.001. Post hoc tests indicated that women with multiple episodes of depression had significantly higher external shame (M 9.51, SD 4.81) than those with

no history of depression (M 5.69, SD 1.54), p=.003; there was no difference with women with a single episode of depression (M 7.18, SD 2.42).

History of anxiety was associated with differences in baseline levels of internal [F(2,107)=4.961, p=.009] and external [F(2,104)=3.201, p=.045] shame. When comparing between groups, post hoc tests did not indicate significant differences in internal shame between women with multiple episodes of anxiety (M 10.30, SD 4.79), a single episode (M 7.15, SD 3.31) or no history of anxiety (M 7.21, SD 3.07). Post hoc tests also did not indicate significant differences in internal shame between women with multiple episodes of anxiety (M 8.99, SD 4.59), a single episode (M 6.67, SD 2.02) or no history of anxiety (M 6.46, SD 2.73).

Participants rated their mood as significantly lower following "STI" information (M 4.37, SD 2.53) compared to following "common" information (M 5.20, SD 2.48), t(109)=5.516, p<.001. Wellbeing scores were also lower following "STI" information (M 4.87, SD 2.54) compared to "common" information (M 5.56, SD 2.50), t(109)=4.687, p<.001. Participants reported more anxiety following "STI" information (M 5.25, SD 2.86) compared to "common" information (M 4.83, SD 2.71) t(109)=-2.293, p=.024.

Discussion

The current study provides new findings on HPV-related shame, anxiety and low mood in women with cervical cancer, with important implications for the treatment and support of patients.

The results provide the first direct evidence that the sexually-transmitted nature of HPV is associated with both internal and external shame in women with cervical cancer. Women experienced higher levels of state shame after reading "STI" information compared to baseline and after "common" information. Information on the high prevalence of HPV was associated with reduced state shame, when compared to "STI" information, although did not reduce lower than it was at baseline.

The results indicate that shame is associated with low mood, anxiety and poor mental wellbeing in women with cervical cancer. Participants reported state reductions in mood and wellbeing, and increased state anxiety after reading "STI" information. In contrast, they experienced improvements in mood and wellbeing and reduced anxiety

after reading “common” information. Furthermore, shame was associated with symptoms of depression and anxiety at baseline, and women who reported a history of repeated episodes of anxiety and depression were at particular risk of experiencing high levels of baseline shame.

While the study was not intended to provide a direct analysis of the model of shame outlined in the introduction, the findings can be interpreted to support the theory that shame consists of both an internally and externally focused component, occurs in the context of cultural stigma and is strongly associated with an emotional response (Gilbert, 2006). The findings indicated that both internal and external shame were heightened following “STI” information, suggesting a possible association between shame and culturally stigmatised sexual permissiveness. The reduced levels of shame observed following “common” information possibly reflect a reduction in cultural stigma, as HPV is then perceived as the norm, rather than the exception. In addition, participants experienced lower mood and increased anxiety following “STI” information, providing evidence of the association between shame and a strong emotional response (Gilbert, 2006).

The findings have implications for patients, acknowledging that many women feel shame when faced with “STI” information, but that the virus is so common that nobody would be justified in judging this negatively.

At a service level, the findings help clinicians to better understand the emotional experiences of patients, not only helping inform how they provide information, but also how they support them through the information and treatment process more generally. The findings provide some specific suggestions for practice:

While clinicians should not fear talking about “STI” information, as patients likely already know this, they should be aware that information and knowledge about the sexual transmission of HPV will likely be associated with increases in shame. Clinicians should carefully consider how “STI” information is presented and how women are supported with this; it may be beneficial to consistently include information about the high prevalence of HPV when discussing it, for example by routinely referring to it as a “very common virus”.

Clinicians may need to generally be vigilant for feelings of shame, for example if a patient is using self-critical language that portrays a sense of shame (for example, “I

think I'm disgusting", "people think I'm a slut"), as they might benefit from active engagement with supportive services. While some patients might benefit from psychological therapy and support [e.g. cognitive behavioural therapy, compassion-focussed therapy (Gilbert, 2009)], frontline non-psychologically trained staff also have a key role in providing empathic and compassionate care. Clinicians can support patients to gently challenge these ideas and find more self-compassion, for example by exploring evidence against negative thoughts, or exploring how they might respond to a friend in the same situation. It is important that clinicians do not invalidate patients' experiences by shutting these conversations down but allow space to talk about these difficult thoughts and feelings. Similarly, the results indicate that shame is associated with increased risk of depression and anxiety (and vice versa), suggesting patients may benefit from opportunities to access formal and informal mental health support for low mood and anxiety.

The results indicate that women with a history of depression and/or anxiety may be at particular risk for high levels of shame. Two brief questions were effective at identifying this risk:

> *Have you ever had a period of time during your life when you were feeling:*
>
> *a. depressed or down most of the day, nearly every day? (a) Yes, once (b) Yes, more than once (c) No*
> *b. very anxious or worried most of the day, nearly every day? (a) Yes, once (b) Yes, more than once (c) No*

This suggests that, if clinicians are unable to routinely screen for mental health problems through lengthier questionnaires, they might ask these two questions at the initial appointment to identify at-risk patients who might need active engagement with supportive services at the time of diagnosis and beyond. It is important to note that these questions cannot replace validated questionnaires, as psychometrics and sensitivity/specificity has not been assessed, but they may have value for clinicians who don't have the skills or time to score and interpret full questionnaires, or in situations where it does not feel appropriate to ask patients to complete lengthy measures.

When thinking at the wider public-health level, the results of the study suggest that patients with cervical cancer may anticipate and expect stigmatising attitudes towards

sexual permissiveness. This reflects the recent survey of the general public by the Eve Appeal found that one fifth of women associated gynaecological cancers with sexual promiscuity and over one third of women believed reducing shame and stigma around gynaecological health and sex would enable them to talk more openly about such health issues (The Eve Appeal, 2015).This suggests that public health campaigns may benefit from targeting stigmatising and shaming attitudes to sexual permissiveness and increase awareness of the prevalence of HPV.

The study has a number of strengths. It is the first study (to the authors' knowledge) that directly explores HPV-related shame, depression and anxiety in women with cervical cancer. The study provides strong evidence that "STI" information is associated with shame and provides evidence of link between shame and depression/anxiety. Methodologically the study was fully powered. However, there were limitations that should also be considered. Brief mood ratings were not recorded at baseline, meaning the only comparison was between mood following "STI" and "common" information. This will have affected interpretation, as it was not possible to compare to a stable baseline or establish whether differences reflect worsening of mood following "STI" information or improvement following "common" information. In addition, the Modified SSGS or the two items indexing history of depression and anxiety were not validated measures. These limitations mean the findings should be treated as preliminary and requiring further research. Finally, it is important to note that the baseline measures of shame, anxiety and depression were not directly linked to experiences of cervical cancer, as general measures were used without reference to their diagnosis. This means it is not possible to directly link the associations between baseline levels of shame, depression and anxiety with experiences with cervical cancer, and instead should consider shame, depression and anxiety in the *context* of cervical cancer. The state measures of shame, mood, wellbeing and anxiety following each level of information were specific to experiences of cervical cancer, however further research should explore the more general experiences of shame associated with diagnosis.

An important future direction for research is to explore factors that might protect against shame associated with "STI" information, for example whether information that HPV is very common could protect against this shame. Modelling this in an experimental setting would require a full cross-over design, which was beyond the

scope of the current project, and wording issues, in which STI information was presented early, meant we were unable to perform any preliminary analyses with the current design. This design would ideally be completed with patients who had no prior "STI" or "common" knowledge, however this is unlikely to be feasible, as the current study found all participants already knew the "STI" information. This design would therefore need to be part of the diagnosis conversations themselves, which might pose an ethical challenge. Qualitative research into experiences of HPV-related shame, depression and anxiety, for example, exploring how patients found out about the STI relationship and how they manage internal and external shame, would also be of significant clinical value in understanding how to support patients.

In conclusion, the current study provides new research on the psychological experiences of women with cervical cancer, providing an understanding of HPV-related shame, depression and anxiety. The results have implications for how to support patients who are at risk of experiencing high levels of shame, in particular around HPV-information provision, identifying at-risk patients, and psychological support for patients.

References

Bjelland, I., Dahl, A. A., Haug, T. T., & Neckelmann, D. (2002). The validity of the Hospital Anxiety and Depression Scale. An updated literature review. *J Psychosom Res, 52*(2), 69-77.

Bradley, S., Rose, S., Lutgendorf, S., Costanzo, E., & Anderson, B. (2006). Quality of life and mental health in cervical and endometrial cancer survivors. *Gynecologic Oncology, 100*(3), 479-486. doi: http://dx.doi.org/10.1016/j.ygyno.2005.08.023

Cancer Research UK. (2016). Cancer Statistics for the UK. Retrieved 14th May 2018

Chambers, S. K., Dunn, J., Occhipinti, S., Hughes, S., Baade, P., Sinclair, S., . . . O'Connell, D. L. (2012). A systematic review of the impact of stigma and nihilism on lung cancer outcomes. *BMC Cancer, 12*, 184-184. doi: 10.1186/1471-2407-12-184

First, M. B., Spitzer, R. L., Gibbon, M., & Williams, J. B. W. (2002). Structured Clinical Interview for DSM-IV-TR Axis I Disorders, Research Version, Patient Edition. (SCID-I/P). In N. Y. S. P. Institute (Ed.). New York: Biometrics Research.

Flynn, S. E. (2010). *Shame, guilt and knowledge of HPV in women recently diagnosed with HPV-related cervical intraepithelial neoplasia (CIN).* (Doctoral), University of Kentucky.

Gilbert, P. (2006). A biopsychosocial and evolutionary approach to formulation with a special focus on shame. In N. Tarrier (Ed.), *Case Formulation in Cognitive Behaviour Therapy*. London and New York: Routledge.

Gilbert, P. (2009). Introducing compassion-focused therapy. *Advances in Psychiatric Treatment, 15*(3), 199-208. doi: 10.1192/apt.bp.107.005264

Kahn, J. A., Slap, G. B., Bernstein, D. I., Tissot, A. M., Kollar, L. M., Hillard, P. A., & Rosenthal, S. L. (2007). Personal meaning of human papillomavirus and Pap test results in adolescent and young adult women. *Health Psychol, 26*(2), 192-200. doi: 10.1037/0278-6133.26.2.192

Kim, S., Thibodeau, R., & Jorgensen, R. S. (2011). Shame, guilt, and depressive symptoms: A meta-analytic review. *Psychological Bulletin, 137*(1), 68-96. doi: 10.1037/a0021466

Maissi, E., Marteau, T. M., Hankins, M., Moss, S., Legood, R., & Gray, A. (2004). Psychological impact of human papillomavirus testing in women with borderline or mildly dyskaryotic cervical smear test results: cross sectional questionnaire study. *Bmj, 328*(7451), 1293. doi: 10.1136/bmj.328.7451.1293

Marschall, D. E., Sanftner, J., & Tangney, J. P. (1994). *The State Shame and Guilt Scale*. Fairfax, VA: George Mason University.

McCaffery, K., Waller, J., Nazroo, J., & Wardle, J. (2006). Social and psychological impact of HPV testing in cervical screening: a qualitative study. *Sex Transm Infect, 82*(2), 169-174. doi: 10.1136/sti.2005.016436

NHS Health Scotland. (2006). Warwick-Edinburgh Mental Well-being Scale.

Shepherd, M. A., & Gerend, M. A. (2013). The blame game: cervical cancer, knowledge of its link to human papillomavirus and stigma. *Psychol Health, 29*(1), 94-109. doi: 10.1080/08870446.2013.834057

The Eve Appeal. (2015). Stigma around gynaecological cancers could be costing lives [Press release]

Vrangalova, Z., Bukberg, R. E., & Rieger, G. (2014). Birds of a feather? Not when it comes to sexual permissiveness. *Journal of Social and Personal Relationships, 31*(1), 93-113. doi: 10.1177/0265407513487638

Vaismoradi, M., Turunen, H., & Bondas, T. (2013). Content analysis and thematic analysis: Implications for conducting a qualitative descriptive study. *Nursing & Health Sciences, 15*(3), 398-405. doi: doi:10.1111/nhs.12048

Waller, J., Marlow, L. A., & Wardle, J. (2007). The association between knowledge of HPV and feelings of stigma, shame and anxiety. *Sex Transm Infect, 83*(2), 155-159. doi: 10.1136/sti.2006.023333

Zigmond, A. S., & Snaith, R. P. (1983). The hospital anxiety and depression scale. *Acta Psychiatr Scand, 67*(6), 361-370.

Blank page

Executive summary of main research project

Amy J Caswell

a.caswell@bath.ac.uk

Internal supervisors: Dr Cara Davis & Dr Megan Wilkinson-Tough

External supervisor: Dr Samantha Cole

Word count: 648

Date of report: 16th May 2018

Cervical cancer is considered a “preventable” cancer, with close to 100% of cases associated with high-risk strains of a common infection, Human Papilloma Virus (HPV). The virus is sexually-transmitted through intimate skin-to-skin contact (Cancer Research UK, 2016). HPV is very common, and it is estimated that at least 80% of people will contract the virus at some point in their life.

Cervical cancer patients are known to be at particular risk of experiencing anxiety, depression and other mental health difficulties, even when compared to patients with other gynaecological cancers (Bradley, Rose, Lutgendorf, Costanzo, & Anderson, 2006). There is some preliminary evidence that these difficulties might be associated with experiences of shame and stigma around the sexual-transmission of HPV. Research has indicated that HPV diagnosis (in the absence of cervical cancer diagnosis) is associated with shame, anxiety and distress (Kahn et al., 2007; Maissi et al., 2004). A recent survey found that one fifth of women associated gynaecological cancers with sexual promiscuity (The Eve Appeal, 2015), and a separate study found that patients in a vignette are rated by others as more “dirty”, “dishonest” and “unwise”, and triggering feelings of moral disgust, when HPV is specified as the cause (Shepherd & Gerend, 2013).

Despite this, there has previously been no research exploring how women with cervical cancer experience HPV information. The current study investigated whether experiences of shame are associated with knowledge of the sexually-transmitted nature of HPV. The study explored three main questions:

1. Is shame in cervical cancer associated with knowledge that HPV is sexually-transmitted?
2. Does information that HPV is very common reduce experiences of shame in women with cervical cancer?
3. Is shame associated with increased depression and anxiety in women with cervical cancer?

One hundred and ten women with cervical cancer completed a repeated measures study, during which they read information that HPV is (1) considered to be a sexually-transmitted virus and (2) very common. Participants completed measures of shame, mood and anxiety after each level of information.

The results indicated that information that HPV is sexually-transmitted is associated with experiences of shame: women experienced higher levels of state shame after reading “STI” information compared to baseline and after “common” information. Information on the high prevalence of HPV was associated with reduced state shame, when compared to “STI” information, although did not reduce lower than it was at baseline. The results indicate that shame is associated with low mood, anxiety and poor mental wellbeing in women with cervical cancer. Participants reported state reductions in mood and wellbeing, and increased state anxiety after reading “STI” information. In contrast, they experienced improvements in mood and wellbeing and reduced anxiety after reading “common” information. Furthermore, shame was associated with symptoms of depression and anxiety at baseline, and women who reported a history of repeated episodes of anxiety and depression were at particular risk of experiencing high levels of baseline shame.

The findings help clinicians to better understand the emotional experiences of patients, not only helping inform how they provide information, but also how they support them through the information and treatment process more generally. The findings provide some specific suggestions for clinical practice, including:

- Be aware of the shame associated with HPV. Consider referring to HPV as a “very common virus” when discussion the sexual-transmission of the virus
- Be alert for indications that patients are experiencing feelings of shame – these patients might benefit from psychological therapy and/or support
- Routinely ask about previous experiences of anxiety and depression, as this can help identify patients particularly at risk for HPV-related shame

In conclusion, the current study provides new research on the psychological experiences of women with cervical cancer, providing an understanding of HPV-related shame, depression and anxiety. The results have implications for how to support patients who are at risk of experiencing high levels of shame, in particular around HPV-information provision, identifying at-risk patients, and psychological support for patients.

References

Bradley, S., Rose, S., Lutgendorf, S., Costanzo, E., & Anderson, B. (2006). Quality of life and mental health in cervical and endometrial cancer survivors. *Gynecologic Oncology, 100*(3), 479-486. doi: http://dx.doi.org/10.1016/j.ygyno.2005.08.023

Cancer Research UK. (2016). Cancer Statistics for the UK. Retrieved 14th May 2018

Kahn, J. A., Slap, G. B., Bernstein, D. I., Tissot, A. M., Kollar, L. M., Hillard, P. A., & Rosenthal, S. L. (2007). Personal meaning of human papillomavirus and Pap test results in adolescent and young adult women. *Health Psychol, 26*(2), 192-200. doi: 10.1037/0278-6133.26.2.192

Maissi, E., Marteau, T. M., Hankins, M., Moss, S., Legood, R., & Gray, A. (2004). Psychological impact of human papillomavirus testing in women with borderline or mildly dyskaryotic cervical smear test results: cross sectional questionnaire study. *Bmj, 328*(7451), 1293. doi: 10.1136/bmj.328.7451.1293

Shepherd, M. A., & Gerend, M. A. (2013). The blame game: cervical cancer, knowledge of its link to human papillomavirus and stigma. *Psychol Health, 29*(1), 94-109. doi: 10.1080/08870446.2013.834057

The Eve Appeal. (2015). Stigma around gynaecological cancers could be costing lives [Press release]

Connecting Narrative

Amy J Caswell

a.caswell@bath.ac.uk

Word count: 2883

Date of report: 16th May 2018

Due to having previously completed a PhD in experimental psychology followed by a postdoc, I started the DClinPsy with experience in research. I have therefore used training to consolidate and develop my research skills in running projects with, and about, clinical populations. Throughout the course I have completed three research projects: The Main Research Project, the Literature Review/Meta-analysis and the Service Improvement Project. I have also completed five case studies, illustrating individual piece of work from each of my placements. All these pieces of work have helped me to develop skills in clinically relevant research, and they are all pieces of work that I am proud of. Perhaps the biggest challenge has been juggling these projects all at once. In order to illustrate the research that I have completed, this connecting narrative will provide an overview of these pieces of work, as well as reflections on my experiences of completing them.

Main research project

Study selection and development

My main research project explored experiences of HPV-related shame, depression and anxiety in women with cancer. It is a project that I am particularly proud of, particularly as HPV-related shame has never previously been explored in women with cervical cancer. I was really engaged with this project throughout my training and have submitted it for publication.

The idea for this project stemmed from the research day that we had early in our first year of training. During the day I had a couple of conversations about shame and health with Dr Megan Wilkinson-Tough and Dr Cara Davis, who would end up as my two supervisors. I took away two ideas focusing on women with cancer – (1) experiences of visible and invisible differences (2) feelings of shame. Looking into the idea around visible and invisible difference, I noticed that the existing literature was extensive and, in some ways, saturated. It felt as if any research would be replicating previous findings, and I wanted to do something more original and impactful. I wanted to move away from completing research for research's sake, i.e. just finding a project because I needed to for DClinPsy requirements.

With this in mind, I kept getting drawn to ideas around shame and women's health. From reading around, I became more aware of the association between HPV and cervical cancer, and this was something that really struck me. I read the Eve Appeal

findings about shame and gynaecological cancer, and also Waller's paper in which they explored shame to hypothetical HPV diagnoses. My previous research has included work around risky sexual behaviour, particularly in men who have sex with men, and I was very aware of how comparatively more open discussion is about men's sexual experiences, and in many ways the more cultural acceptance there is around men having sex. Shame and cervical cancer seemed a natural and exciting avenue of research for me to pursue and I was struck by how little research there is available in this field, and how important this felt to remedy.

I was initially drawn to adapting the Waller paper (which I ended up doing) but had some concerns about the ethical implications of asking patients about their experiences of shame. I went back and forth and back and forth over different research designs, before emailing Dr Davis and Dr Wilkinson-Tough some suggestions. We ended up meeting, debating the different ideas, before settling on my original idea of adapting the Waller paper. To ensure it felt appropriate and relevant, I consulted with a woman who had previously had cervical cancer, who gave me some advice around wording.

Ethical approval and recruitment

Once I had decided on my design, the next step was deciding recruitment strategy, which, in term, determined which ethical approval bodies I was required to approach.

Recruitment was initially a worry as Dr Samantha Cole (my field supervisor) at UHBristol was concerned about the likelihood of being able to recruit sufficiently from the service. Dr Cole also wondered whether clinicians might be nervous about distributing a questionnaire about experiences of shame. At this point I decided that online recruitment might be the most successful approach. To reduce the burden of ethical approval applications, and to get the project off the ground as quickly as possible, I decided to apply for ethics through the university, and recruit online, and then only apply for NHS ethics if numbers were too low and I needed to try to find more participants through the NHS. However, I quickly realised a flaw with this plan – that if I subsequently applied for NHS approval, and was asked to make significant changes, that I would end up with two versions of the study (one University approved, and the other NHS approved). As such, I decided to apply through both NHS and university ethics, and recruit through both the NHS and online simultaneously. To

maximise my chances, I also approached Dr Sue Gessler, a clinical psychologist working in the field at UCL, who kindly agreed to be involved in the project, and recruit through my second NHS site. Around this time Dr Cole went on maternity leave, and Dr Jennie Norris kindly supported recruitment at UHBristol.

Despite my initial worries, recruitment went well, and I met my target, which was a huge relief. I was initially hoping for more NHS recruitment (I think I ended up with three participants from the two NHS sites in total) but was pleased to have had the experience of applying for NHS ethics – it was a useful opportunity to get experience of this.

Data analysis and write up

I completed data analysis myself, with minimal support from supervisors. I wrote up the project with comments on multiple drafts from university supervisors and Dr Gessler (Dr Cole was on maternity leave during this time).

Contributions to clinical practice

Women with cervical cancer's experience of HPV information is a poorly understood area. The project contributes to our understanding of the impact of this information, particularly information on the sexual-transmission of HPV. The project gives several recommendations for clinical practice, specifically around how clinicians can best support patients through the diagnosis and information process and beyond. Based on my findings, future directions for further research were recommended.

Challenges and personal learning

I was lucky enough that my main research felt fairly straightforward throughout. As I felt so passionate about the project I was motivated to complete it and was excited to find our hypotheses were supported. I took learning from it at both a research and clinical level. At the research level, I learnt skills in how to run studies with participants from a clinical group, with a very limited budget. At a clinical, and perhaps personal, level, the project really highlighted to me the psychological and emotional impact a diagnosis of cervical cancer. I found myself becoming more and more impassioned about the experiences of my participants and I feel that this project has extended beyond my research and helped me to become a more aware clinician.

Experiences of shame are now at the forefront of my mind in much of my clinical work.

Critical review of the literature

Study selection

My critical review was the last of my projects that I developed an idea for. The idea was developed in conjunction with Dr Jo Daniels, an expert in the field of Chronic Fatigue Syndrome (CFS), as she had identified a gap in the literature. Together we initially planned a briefer systematic review, which simply summarised the prevalence of anxiety and depression in CFS. With time and discussion, we ended up deciding to extend this to include a meta-regression of the impact of anxiety and depression on treatment outcomes. This extension made the project feel more clinically relevant and felt as if the project would have real value for clinicians and researchers.

Data analysis

As I did not have experience in running meta-analyses or meta-regression, I approached a couple of different people for support with the analysis. Dr Ian Walker gave me some initial advice, however was not able to help further. I then approached Adam von Ende, a friend not affiliated with the university, who was able to offer support and advice with the data analysis. Mr von Ende is to be included as an author on any papers arising from the project.

Contributions to the literature

The review highlighted the prevalence of anxiety and depression in CFS and found evidence that depressive symptoms may be associated with poorer treatment outcomes in physical functioning. These findings have implications for the support and care of patients with CFS, suggesting that their emotional and psychological needs should be carefully considered as part of their support.

Challenges and personal learning

CFS is a complex condition that is poorly understood. As I developed this project, and immersed myself more in the literature, I became increasingly aware of the frustration many patients feel, and their experiences of feeling misunderstood and criticised by health professionals. It is evident that many patients feel very dismissed by clinicians,

and this was something I was keen not to do. I was careful in the write up not to dismiss experiences or suggest in any way that the condition may be psychological. This experience encouraged me to reflect on how a patient might experience my research if they were to read it in a journal or article. This is something that I have not always considered in the past, instead mostly focusing on how a colleague, academic or clinician might experience the work.

At a skills level, this project enabled me to develop skills in completing a systematic review, running meta-analyses and meta-regressions, none of which I had done before. The project was challenging and time consuming, but I am ultimately proud of it.

Service Improvement Project

Study selection and development

During my working age adults placement in the B&NES Therapies Service, I was supervised by Dr Hanna van der Woude. Dr van der Woude was in the process of developing the "My Wellbeing Toolkit", which she planned to introduce to the Recovery Service. During my placement we discussed the idea of me completing my service improvement project (SIP) on the booklet, to explore experiences of using it. Dr Emma Griffith came on board as my course supervisor.

We initially planned to explore both clinician and client experiences of using the booklet, using both quantitative and qualitative methods. However, at the university Project Approval Session (PAS), the assessors felt that including both clinicians and clients was too large a project and would not be feasible in the time frame. They also felt that the initial proposal had not adequately considered that clinicians might not have been using the booklet. Based on this, we revised the project to include an exploration of usage patterns of the booklet, and Recovery Service clinician experiences of the booklet. We decided not to explore client experiences of the booklet, as this would have not been feasible if it transpired that clinicians had not shared the booklet with them.

Ethical approval

Following discussions with the B&NES Research and Development department, the project was deemed service-evaluation and not research. I was therefore required to

apply for service-evaluation approval from the trust, and ethical approval from the University of Bath.

Process of completing the SIP

I completed all data collection and analysis myself. The write up was completed with comments on drafts from Dr Griffith.

Challenges and personal learning

I found the SIP to be my most challenging project for several reasons.

I had very changeable field supervision on the project. My first supervisor who I developed the project in conjunction with, Dr van der Woude, went on maternity leave immediately before the Project Approval Session. This meant that she was unable to contribute to the changes requested by the panel. Supervision was initially covered by Dr Claire Williamson, a senior clinical psychologist in the trust. I met with Dr Williamson on a couple of occasions, however she was unable to remain my supervisor after her time became more restricted after taking on a more senior role within the trust. At this point, my supervision transferred to Dr Chris Gillmore, who I met with on a couple of occasions, before Dr van der Woude returned to work. This changing supervision on the project felt inconsistent and lacked continuity. Each supervisor tried to provide consistency with the previous supervisors, however in reality this was difficult to implement.

Leading on from this, and perhaps affected by the changing supervision, I underestimated how difficult it would be to recruit clinicians to the project. I think that not being fully engaged with one supervisor in the trust made it difficult to engage with the recovery team. As we wanted the team to have had ample opportunity to use the booklet, we also had a time restriction in that we had to wait to collect data. This meant that I was no longer working in the trust at the time of recruitment/data collection. As I had never worked within the Recovery Service, I did not have a working relationship with any clinicians within the service. Together these factors impacted on recruitment, and I was disappointed that my numbers of returned questionnaires were so low. I made multiple attempts to recruit and feel that this effort is not reflected in the project output.

This project was the first time that I have ever completed qualitative analysis. This was a real learning curve for me and took me totally out of my comfort zone. I am much more familiar with quantitative analysis and found it challenging to move away from this more structured approach.

Reflecting on the project, I am aware that I found it difficult to meet the needs of the specific service, whilst also completing a project that had meaning beyond the scope of the particular team and resource. As the focus group schedule and questionnaire were specific to the particular resource, the questions were inherently constrained to the service. It may have been useful to have a wider focus, thinking about mind-map based resources more generally, and this might have resulted in more generalisable findings. At the same time, the service requested that the project was specific to the particular resource, and it was hard to balance these conflicting needs. When considering how I would take a similar project forward in the future, I would aim to spend more time in the planning stage considering how I could meet both the needs of the service and contribute more generalisable findings.

Contributions to clinical practice

Brief interventions that do not sacrifice clinical effectiveness are a burgeoning area of research. This project provides preliminary evidence that mind-map based booklets are experienced as useful by clinicians, when working in secondary care mental health. The project identified that there are, however, barriers to use that need to be addressed. Based on these findings, and to ensure clinical utility, we recommend that a future project explores client experiences of using the booklet.

Case studies

I found writing case studies one of the more challenging aspects of placement, but they also helped me to develop important clinical skills.

My case studies required me to carefully consider my clinical practice, both alongside and following my sessions. A key aspect of writing a case study is clarifying the theory-practice links – the process helped me to focus on these, and not just plough on without considering theory and the literature. Another key component was completing regular outcome measures. This experience helped me to consider the

importance of routine evaluation and gave me experience of using measures outside of a research environment.

My case studies have varied considerably, in terms of client and content. The vast majority of my cases throughout training were complex – it would have been nice to have had some more "straightforward" IAPT clients, in which outcome measures and treatment protocols were provided to me. The complexity meant that at times I found it difficult to put my work into a structured and organised case study and would spend days and weeks trying to do so. I am pleased with the case studies that I have produced, however would have appreciated more space to complete reflective case studies, which did not need to be so structured. I had some interesting cases and dilemmas throughout training, that I would have liked to have been able to write about.

Anticipated post-qualification research

As I commented at the beginning of this narrative, one of the biggest challenges of training has been completing three pieces of research/service improvement, alongside my case studies (and consultation project, which hasn't been mentioned in this narrative). Juggling all three projects – holding them in mind, recruiting, running the analysis, reading 1000+ abstracts for my critical review, etc – has at times felt overwhelming and unmanageable. Despite this, I have managed it. The learning I have taken from this experience has been enormous. I have learnt how to complete clinically relevant research, and I think that I am a far better researcher for it.

I am keen to continue to expand my research experience throughout my career as a clinical psychologist. This training has given me the skills to manage research alongside direct clinical work and has also given me the tools to complete research that can have an impact on clinical practice. One of my frustrations with my previous academic research experience was the lack of clinical impact, and it has been a real pleasure to no longer feel this frustration.

My ambition is to continue with research in the field of clinical health. I anticipate that conducting research alongside clinical work will not always be easy. I can imagine that a busy workload and other service-related pressures will be a major barrier to completing further research. I hope that I can partly address this by continuing with links at the university, and hopefully agreeing some research time

into a job plan. I plan to find out whether it would be possible to supervise a future bath trainee on their own research project.

In conclusion, my research projects have been challenging, but ultimately greatly rewarding. I am immensely proud of the work I have completed, and hope that you, the reader, feel that this is justified.

Acknowledgements

I am profoundly grateful to the many individuals who have supported me both academically and personally throughout the three years.

I would like to thank Dr Jo Daniels, on many counts – for supervising my Literature Review, for being my clinical tutor, and for the general career support and guidance she has offered me. I would like to thank my supervisors for my Main Research Project, Dr Cara Davis and Dr Megan Wilkinson-Tough, whose support and encouragement has been invaluable. I would also like to thank Dr Samantha Cole, Dr Jennie Norris and Dr Sue Gessler for their support with the project. For my Service Improvement Project, I wish to thank my university supervisor Dr Emma Griffith, and the many field supervisors who supported/stepped in for the project – Dr Hanna van der Woude, Dr Chris Gillmore and Dr Claire Williamson. For my Literature Review, alongside Dr Jo Daniels, thank you to Adam von Ende, for support with my statistical analysis. Thanks to a number of people who were influential in completing my consultancy project: Gordon Benson, Lauren Evans and Dr Jon Cash. Thanks also to all of those who gave their time to participate in my research and consultation projects.

I would also like to thank my placement supervisors throughout training, who have guided me throughout my clinical work, and each of the clients who consented to have the work we completed written-up.

Finally, I would like to thank my partner, friends, family and fellow trainees who have all been incredible throughout my training – thank you, you've all been brilliant.

Dr Amy J Caswell

University of Bath

May 2018

Blank page

APPENDICES

Literature review appendices

Appendix A – BMJ Instructions for authors

Research

We have produced a checklist to help authors decide whether *The BMJ* is the right journal for their research. If the work does not seem to fit in *The BMJ*, it may be better sent straight to another journal with a more specialist or local readership or a higher acceptance rate.
To learn more about the kind of research articles we give priority to, and what services we offer to authors of research, please read the editorial "Publishing your research study in the *BMJ*?". Please note that we welcome studies - even with "negative" results - as long as their research questions are important, new, and relevant to general readers and their designs are appropriate and robust.

Word count and style

To encourage full and transparent reporting of research we do not set fixed word count limits for research articles. Nonetheless, we ask you to make your article concise and make every word count. You will be prompted to provide the word count for the main text (excluding the abstract, references, tables, boxes, or figures) when you submit your manuscript.
Original research articles should follow the IMRaD style (introduction, methods, results, and discussion) and should include a structured abstract (see below), a structured discussion, and a succinct introduction that focuses - in no more than three paragraphs - on the background to the research question.
For an intervention study, the manuscript should include enough information about the intervention(s) and comparator(s) (even if this was usual care) for reviewers and readers to understand fully what happened in the study. To enable readers to replicate your work or implement the interventions in their own practice, please also provide any relevant detailed descriptions and materials (uploaded as one or more supplemental files, including video and audio files where appropriate). Alternatively, please provide in the manuscript URLs to openly accessible websites where these materials can be found.
Please ensure that the discussion section of your article comprises no more than a page and a half and follows this overall structure, although you do not need to signpost these elements with subheadings:
• *Statement of principal findings*
• *Strengths and weaknesses of the study*
• *Strengths and weaknesses in relation to other studies, discussing important differences in results*
• *Meaning of the study: possible explanations and implications for clinicians and policymakers*
• *Unanswered questions and future research*
This video gives more detailed advice on writing each section of a research paper for *The BMJ*.

Structured abstract

Please ensure that the structured abstract is as complete, accurate, and clear as possible and has been approved by all authors. We may screen original research articles by reading only the abstract.
Abstracts should be 250- 300 words long: you may need up to 400 words, however, for a CONSORT or PRISMA style abstract. MEDLINE can now handle up to 600 words.
Abstracts should include the following headings, but they may be modified for abstracts of clinical trials or systematic reviews and meta-analyses according to the requirements on the the CONSORT extension for abstracts and the PRISMA extension for abstracts, respectively.
• **Objectives** - a clear statement of the main aim of the study and the major hypothesis tested or research question posed
• **Design** - including factors such as prospective, randomisation, blinding, placebo control,

case control, crossover, criterion standards for diagnostic tests, etc.
• **Setting** - include the level of care, eg primary, secondary; number of participating centres. Be general rather than give the name of the specific centre, but give the geographical location if this is important
• **Participants (instead of patients or subjects)** - numbers entering and completing the study, sex, and ethnic group if appropriate. Give clear definitions of how selected, entry and exclusion criteria.
• **Interventions** - what, how, when and for how long. This heading can be deleted if there were no interventions but should normally be included for randomised controlled trials, crossover trials, and before and after studies.
• **Main outcome measures** - those planned in the protocol, those finally measured (if different, explain why).
• **Results** - main results with (for quantitative studies) 95% confidence intervals and, where appropriate, the exact level of statistical significance and the number need to treat/harm. Whenever possible, state absolute rather than relative risks.
• **Conclusions** - primary conclusions and their implications, suggesting areas for further research if appropriate. Do not go beyond the data in the article. Conclusions are important because this is often the only part that readers look at.
• **Trial registration** - registry and number (for clinical trials and, if available, for observational studies and systematic reviews).
When writing your abstract, use the active voice but avoid "we did" or "we found". Numbers over 10 do not need spelling out at the start of sentences. p-values should always be accompanied by supporting data, and denominators should be given for percentages. Confidence intervals should be written in the format (15 to 27) within parentheses, using the word "to" rather than a hyphen. Abstracts do not need references.

Statistical issues

We want your piece to be easy to read but also as scientifically accurate as possible. We encourage authors to review the "Statistical Analyses and Methods in the Published Literature or The SAMPL Guidelines" while preparing their manuscript.
Whenever possible, state absolute rather than relative risks. Please include in the results section of your structured abstract (and in the article's results section) the following terms, as appropriate:
For a clinical trial:
• Absolute event rates among experimental and control groups.
• RRR (relative risk reduction).
• NNT or NNH (number needed to treat or harm) and its 95% confidence interval (or, if the trial is of a public health intervention, number helped per 1000 or 100,000).
For a cohort study:
• Absolute event rates over time (eg 10 years) among exposed and non-exposed groups
• RRR (relative risk reduction)
For a case control study:
• OR (odds ratio) for strength of association between exposure and outcome
For a study of a diagnostic test:
• Sensitivity and specificity
• PPV and NPV (positive and negative predictive values)
The box stating 'what is known' and 'what this study adds' should also reflect accurately the above information. Under what this study adds, please give the one most useful summary statistic eg NNT.
Please do not use the term 'negative' to describe studies that have not found statistically significant differences, perhaps because they were too small. There will always be some uncertainty, and we hope you will be as explicit as possible in reporting what you have found in your study. Using wording such as "our results are compatible with a decrease of this much or an increase of this much" or 'this study found no effect' is more accurate and helpful to readers than "there was no effect/no difference." Please use such wording

throughout the article, including the structured abstract and the box stating what the paper adds.
Provide one or more references for the statistical package(s) used to analyse the data - for example, RevMan for a systematic review. There is no need to provide a formal reference for a very widely used package that will be familiar to general readers - for example, Stata - but please say in the text which version you used.

Reporting guidelines

Reporting guidelines promote clear reporting of methods and results to allow critical appraisal of the manuscript. We ask that all manuscripts be written in accordance with the appropriate reporting guideline. Please submit as supplemental material the appropriate reporting guideline checklist showing on which page of your manuscript each checklist item appears. A complete list of guidelines can be found in the website of the Equator Network. Below is the list of most often used checklists but others may apply.
For a **clinical trials**, use the CONSORT checklist and also include a structured abstract that follows the CONSORT extension for abstract checklist, the CONSORT flowchart and, where applicable, the appropriate CONSORT extension statements (for example, for cluster RCTs, pragmatic trials, etc.). A completed TIDieR checklist is also helpful as this helps to ensure that trial interventions are fully described in ways that are reproducible, usable by other clinicians, and clear enough for systematic reviewers and guideline writers.
For **systematic reviews or meta-analysis** of randomised trials and other evaluation studies, use the PRISMAchecklist and flowchart and use the PRISMA structured abstract checklist when writing the structured abstract.
For **studies of diagnostic accuracy**, use the STARD checklist and flowchart.
For **observational studies**, use the STROBE checklist and any appropriate extension STROBE extensions.
For **genetic risk prediction studies,** use GRIPS.
For **economic evaluation studies**, use CHEERS.
For **studies developing, validating or updating a prediction model**, use TRIPOD.
For articles that include explicit statements of the quality of evidence and strength of recommendations, we prefer reporting using the GRADE system.

Cover letter

A cover letter is your opportunity to introduce your study to the editor, highlighting the most important findings and novelty. Please also include in the letter the following information:
• Details of previous publications from the same study - including in scientific abstracts or partial reports by the media at scientific meetings and in foreign language journals.
• Details of any previous publication of the same study in electronic form, including on any preprint server. For example, *The BMJ* does not consider posting of protocols and results in clinical trials registries to be prior publication, but we would like to know if results have been posted, and where (please provide URLs or trial registration details). And we are pleased to consider articles based on longer systematic reviews and meta-analyses published at the Cochrane Library or HTA database.
• In most cases, we will follow suggestions for preferred and non-preferred reviewers. If you have suggestions for preferred reviewers, please provide us with their names and contact details; we may invite some of them to review the paper. Please also let us know if you would not like us to invite specific reviewers to look at your work but provide an explanation for your request.
• Assurance that a study funded or sponsored by industry follows the guidelines on good publication practice.These GPP2 guidelines aim to ensure that such studies are published in a responsible and ethical manner. The guidelines cover companies' responsibility to endeavour to publish results of all studies, companies' relations with investigators, measures to prevent redundant or premature publication, the roles of authors and contributors, and the role of professional medical writers.
• Assurance that any article written by a professional medical writer follows the guidelines

by the European Medical Writers' Association on the role of professional medical writers. The guidelines emphasise the importance of respecting widely recognised authorship criteria, and in particular of ensuring that all people listed as named authors have full control of the content of articles. The role of professional medical writers must be transparent. Please name any professional medical writer among the list of contributors to any article for *The BMJ* (not only original research articles), and specify in the formal funding statement for the article who paid the writer. Writers and authors must have access to relevant data while writing articles. Medical writers have professional responsibilities to ensure that the articles they write are scientifically valid and are written in accordance with generally accepted ethical standards.

Mandatory patient and public involvement reporting

The BMJ is encouraging active patient and public involvement in clinical research as part of its patient partnership strategy. This is research which is "co produced" *with* patients, carers, or members of the public. Patient involvement in this context is not about being a research participant, answering surveys, or being an interviewee. It encompasses setting research priorities, defining research questions and outcome measures, providing input into study design and conduct, dissemination, or results and evaluation.

To support co production of research we request that authors provide a **Patient and Public Involvement**statement in the methods section of their papers. We request this to both encourage the movement and ensure that BMJ readers can easily see whether, and if so how, patients and the public were involved in the research. If they were not involved in any way this information should be formally documented in the Patient and Public Involvement statement.

As co production of research with patients and the public is relatively new we appreciate that not all authors will have involved them in their studies. We also appreciate that patient/public involvement may not be feasible or appropriate for all papers. We therefore continue to consider papers where they were not involved.

The Patient and Public Involvement statement should provide a brief response to the following questions, tailored as appropriate for the study design reported:

At what stage in the research process were patients/public first involved in the research and how?

• How were the research question(s) and outcome measures developed and informed by their priorities, experience, and preferences?

• How were patients/public involved in the design of this study?

• How were they involved in the recruitment to and conduct of the study?

• Were they asked to assess the burden of the intervention and time required to participate in the research?

In addition to considering the points above we advise authors to look at guidance for best reporting of patient and public involvement as set out in the GRIPP2 reporting checklist. Even if patients were not involved in the study described, we suggest that you consider enlisting their help in disseminating the research findings.

If information detailing whether there was patient and public involvement, or not, is missing in the submitted manuscript we will request authors to provide it.

Where they have been involved we consider it good practice for authors to name and thank them in the contributorship statement after seeking their permission to do so; and to clearly identify them as patient/public contributors. When they have contributed substantially and meet authorship criteria they should be invited to coauthor the manuscript.

Please note also note that it's *The BMJ* policy to send relevant research papers for review by patient reviewersalongside academic peer reviewers.

Links to selected examples of Patient and Public Involvement statements in published BMJ research papers showing patient and carer involvement at various stages of the research process.

Comparison of the two most commonly used treatments for pyoderma gangrenosum: results of the STOP GAP randomised controlled trial

Evidence based community mobilization for dengue prevention in Nicaragua and Mexico

Computerised cognitive behaviour therapy (cCBT) as treatment for depression in primary care (REEACT trial): large scale pragmatic randomised controlled trial.

Real world effectiveness of warfarin among ischemic stroke patients with atrial fibrillation: observational analysis from Patient-Centered Research into Outcomes Stroke Patients Prefer and Effectiveness Research (PROSPER) study.

Example PPI statements to adapt for use in a paper

Examples to guide the wording for PPI statements

Data sharing

We require a data sharing statement for all research papers. For papers that do not report a trial, we do not require that the authors agree to share the data, just that they say whether they will.

For reports of clinical trials, we ask that the authors commit to making the relevant anonymised patient level data available on reasonable request (see editorial). This policy applies to any research article that reports the main endpoints of a randomised controlled trial of one or more drugs or medical devices in current use, whether or not the trial was funded by industry.

"Relevant data" encompasses all anonymised data on individual patients on which the analysis, results, and conclusions reported in the paper are based. As for "reasonable request," *The BMJ* is not in a position to adjudicate, but we will expect requesters to submit a protocol for their re-analysis to the authors and to commit to making their results public. We will encourage those requesting data to send a rapid response to thebmj.com, describing what they are looking for. If the request is refused we will ask the authors of the paper to explain why.

In addition, we will follow the new ICMJE data sharing policy that goes into place on July 1, 2018 (see editorial): manuscripts submitted to ICMJE journals that report the results of clinical trials must contain a data sharing statement that indicates whether individual de-identified participant data (including data dictionaries) will be shared; what data in particular will be shared; whether additional, related documents will be available (study protocol, statistical analysis plan, etc); when the data will become available and for how long; by what access criteria data will be shared (including with whom, for what types of analyses, and by what mechanism). Clinical trials that begin enrolling participants on or after January 1, 2019 must also include a data sharing plan in the trial's registration. If the data sharing plan changes after registration this should be reflected in the statement submitted and published with the manuscript, and updated in the registry record.

We encourage authors of all research articles in *The BMJ* to link their articles to the raw data from their studies. For clinical trials, we require data sharing on request as a minimum and- if authors of such trials are willing to go further and share the data openly, so much the better. *The BMJ* has partnered with the Dryad digital repository datadryad.org to make open deposition easy and to allow direct linkage by doi from the dataset to *The BMJ*'s article and back (for *The BMJ*'s articles' datasets see here).

Data requesters should do the following:

• Submit a rapid response to the paper and email the corresponding author for the paper to request the relevant data.

• Be prepared to provide the authors of the paper a detailed protocol for your proposed study, and to supply information about the funding and resources you have to carry out the study.

• If appropriate, invite the original author[s] to participate in the re-analysis.

• If a month elapses without a response from the authors, please email the head of research for The BMJ (presently eloder@bmj.com) and cc papersadmin@bmj.com.

• The BMJ will assess the request and if appropriate we will encourage the authors or their institution to share the data, although we are not in a position to compel data release or broker agreements. Our role is limited to making the request process public, and all correspondence related to the request may be made public through rapid responses to the paper.

Statements that must be included in Research submissions (Ethics approval, funding, and tranparency)

Ethics approval

All research studies published in *The BMJ* should be morally acceptable, and must follow the World Medical Association's Declaration of Helsinki. To ensure this, we aim to appraise the ethical aspects of any submitted work that involves human participants, whatever descriptive label is given to that work including research, audit, and sometimes debate. This policy also applies on the very rare occasions that we publish work done with animal participants. The manuscript must include a statement that the study obtained ethics approval (or a statement that it was not required), including the name of the ethics committee(s) or institutional review board(s), the number/ID of the approval(s), and a statement that participants gave informed consent before taking part.

Transparency statement

Please include in your manuscript a transparency declaration: a statement that the lead author (the manuscript's guarantor) affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as originally planned (and, if relevant, registered) have been explained.

The BMJ is committed to making the editorial process transparent and ethical. *The BMJ*'s transparency policies are accessible from this link.

Role of the funding source

Please include in the manuscript a statement giving the details of all sources of funding for the study. As appropriate, the statement must include a description of the role of the study sponsor(s) or funder(s), if any, in the study design; in the collection, analysis, and interpretation of data; in the writing of the report; and in the decision to submit the article for publication. In addition, the statement must confirm the independence of researchers from funders and that all authors, external and internal, had full access to all of the data (including statistical reports and tables) in the study and can take responsibility for the integrity of the data and the accuracy of the data analysis is also required.

If you are submitting an original article reporting an industry sponsored clinical trial, postmarketing study, or other observational study please follow the guidelines on good publication practice (GPP2) and on properly reporting the role of professional medical writers. Another resource, the Authors' Submission Toolkit: A practical guide to getting your research published summarises general tips and best practices to increase awareness of journals' editorial requirements, how to choose the right journal, submission processes, publication ethics, peer review, and effective communication with editors - much of which has traditionally been seen as mysterious to authors.

The BMJ will *not* consider for publication any study that is partly or wholly funded by the tobacco industry, as explained in this editorial.

Patient and Public Involvement statement

Within the Methods section of your paper, please state if and how patients and the public were involved in the research you are describing. For more information, please see the specific guidance on mandatory reporting of patient and public involvement above. If patients and the public were not involved this information should be formally documented in the Patient and Public Involvement statement.

Summary boxes

Please produce a box offering a thumbnail sketch of what your article adds to the literature. The box should be divided into two short sections, each with 1-3 short sentences.

Section 1: What is already known on this topic

In two or three single sentence bullet points, please summarise the state of scientific knowledge on this topicbefore you did your study, and why this study needed to be done. Be clear and specific, not vague.

Section 2: What this study adds

In one or two single sentence bullet points, give a simple answer to the question “What do we now know as a result of this study that we did not know before?” Be brief, succinct, specific, and accurate. For example: "Our study suggests that tea drinking has no overall benefit in depression." You might use the last sentence to summarise any implications for practice, research, policy, or public health. For example, your study might have asked and answered a new question (one whose relevance has only recently become clear); contradicted a belief, dogma, or previous evidence provided a new perspective on something that is already known in general; or provided evidence of higher methodological quality for a message that is already known. DO not make statements that are not directly supported by your data.

Appendix B –Full search terms

Pubmed:

("chronic fatigue syndrome" OR “chronic fatigue disorder” OR "myalgic encephalomyelitis" OR “myalgic encephalopathy” OR “CFS” OR “CFS/ME” OR “ME/CFS”) AND (“Cognitive behavioural therapy” OR “cognitive therapy” OR “cognitive behavioral therapy” OR “behavioural therapy” OR “behavioral therapy” OR “graded exercise therapy” OR “exercise therapy” OR “exercise” OR “activity” OR “activity management” OR “cognitive behaviour therapy” OR “cognitive behavior therapy” OR “behaviour therapy” OR “behavior therapy”) AND (randomized controlled trial[pt] OR controlled clinical trial[pt] OR randomized[tiab] OR placebo[tiab] OR drug therapy[sh] OR randomly[tiab] OR trial[tiab] OR groups[tiab] NOT (animals [mh] NOT humans [mh]))

PsycINFO:

("chronic fatigue syndrome" OR “chronic fatigue disorder” OR "myalgic encephalomyelitis" OR “myalgic encephalopathy” OR “CFS” OR “CFS/ME” OR “ME/CFS”) AND (“Cognitive behavioural therapy” OR “cognitive therapy” OR “cognitive behavioral therapy” OR “behavioural therapy” OR “behavioral therapy” OR “graded exercise therapy” OR “exercise therapy” OR “exercise” OR “activity” OR “activity management” OR “cognitive behaviour therapy” OR “cognitive behavior therapy” OR “behaviour therapy” OR “behavior therapy”) AND (random* OR control* OR SU.EXACT.EXPLODE(treatment))

Embase:

("chronic fatigue syndrome" OR “chronic fatigue disorder” OR "myalgic encephalomyelitis" OR “myalgic encephalopathy” OR “CFS” OR “CFS/ME” OR “ME/CFS”) AND (“Cognitive behavioural therapy” OR “cognitive therapy” OR “cognitive behavioral therapy” OR “behavioural therapy” OR “behavioral therapy” OR “graded exercise therapy” OR “exercise therapy” OR “exercise” OR “activity” OR “activity management” OR “cognitive behaviour therapy” OR “cognitive behavior therapy” OR “behaviour therapy” OR “behavior therapy”) AND ('crossover procedure':de OR 'double-blind procedure':de OR 'randomized controlled trial':de OR 'single-blind procedure':de OR (random* OR factorial* OR crossover* OR cross NEXT/1 over* OR placebo* OR doubl* NEAR/1 blind* OR singl* NEAR/1 blind* OR assign* OR allocat* OR volunteer*):de,ab,ti)

Appendix C –List of authors contacted

Reference	Action	Outcome
Broadbent 2016 & 2017	Emailed to request any available anxiety and/or depression data	No response; paper excluded
Deale 1997	Emailed to confirm lower age range of participants. Emailed to request any available anxiety data.	No response; paper included (no anxiety data available)
Deale 2001	Emailed to request any available anxiety and/or depression data	No response; paper excluded
Fulcher 1997	Emailed to confirm age range of included participants	No response; paper included
Lattie 2016	Emailed to request anxiety and/or depression data for their different groups	No response; paper excluded
Nunez 2011	Emailed to confirm age range of included participants	Author responded confirming adult sample; paper excluded as combination therapy
Prins 2001	Emailed to ask if a specific measure of anxiety/depression was recorded (they refer to generic SCL-90 questionnaire in text)	No response; paper excluded
Sharpe 2015	Emailed to request any available anxiety and/or depression data corresponding to long-term follow-up sample	No response; paper excluded
Tummers 2010 & 2012	Emailed authors to establish whether they consider intervention CBT	No response; paper excluded as anxiety/depression data unavailable
Vos-Vromans 2016	Emailed to request anxiety and/or depression data for their different groups	No response; paper excluded
Wiborg 2015	Emailed to ask if a specific measure of anxiety/depression was recorded (they refer to generic SCL-90 questionnaire in text)	No response; paper excluded
Knoop 2008	Emailed to request anxiety and/or depression data for their different groups	No response; paper excluded
Sharpe 1996	Emailed to ask for additional data from paper	Author responded stating data is unavailable
Wearden 1998	Emailed to ask for additional data from paper	No response
Researcher	**Action**	**Outcome**
Prof. Michael Sharpe	Contacted author to request any unpublished data	Researcher responded - No data available
Prof. Trudie Chalder	Contacted author to request any unpublished data	Researcher responded - No data available

Prof. Esther Crawley	Contacted author to request any unpublished data	No response from researcher
Prof. Peter white	Attempted to contact author to request any unpublished data	No email address available
Dr. Hazel O'Dowd	Contacted author to request any unpublished data	Researcher responded - No data available
Dr. Maria Loades	Contacted author to request any unpublished data	Researcher responded - No data available

Appendix D –List of borderline papers resolved through discussion

Papers reporting general measure of psychological wellbeing/distress, but not a specific measure of anxiety/depression:	
Prins 2001	Paper reports SCL-90
Vos-Vromans 2016	Paper reports SCL-90
Wiborg 2015	Paper reports SCL-90
Lopez 2011	Paper reports POMS total mood disturbance
Tummers 2012	Paper reports brief symptom inventory
Papers that include components of CBT but not full intervention:	
Friedberg 2016	Intervention applies components of CBT but not full protocol
Rimes 2013	Mindfulness based CBT intervention
Surawy 2005	Mindfulness based CBT intervention
Thomas 2006	Multiconvergent combination treatment including aspects of CBT/GET/others
Thomas 2008	Multiconvergent combination treatment including aspects of CBT/GET/others
Wearden 2010	Pragmatic rehabilitation with aspects of CBT
Nunez 2011	Combination treatment
No suitable control condition:	
Burgess 2012	Face-to-face compared to telephone CBT
Windthorst 2017	GET vs an active "HRV-biofeedback treatment"
Other:	
Strang 2002	Participants with certain comorbid physical health conditions (e.g. mitral valve prolapse and hypoglycaemia) were not excluded
Vos-Vromans 2016b	Secondary analysis of data; excluded because paper did not include a suitable control group

THE COCHRANE COLLABORATION®

Data collection form

Intervention review – RCTs and non-RCTs

This form can be used as a guide for developing your own data extraction form. Sections can be expanded and added, and irrelevant sections can be removed. It is difficult to design a single form that meets the needs of all reviews, so it is important to consider carefully the information you need to ~~collect, and~~ design your form accordingly. Information included on this form should be ~~comprehensive, and~~ may be used in the text of your review, 'Characteristics of included studies' table, risk of bias assessment, and statistical analysis.

Notes on using a data extraction form:

- Be consistent in the order and style you use to describe the information for each included study.
- Record any missing information as unclear or not described, to make it clear that the information was not found in the study report(s), not that you forgot to extract it.
- Include any instructions and decision rules on the data collection form, or in an accompanying document. It is important to practice using the form and give training to any other authors using the form.
- You will need to protect the document ~~in order to~~ use the form fields (Tools / Protect document)

Review title or ID
Depression and anxiety CFS/ME

Study ID *(surname of first author and year first full report of study was published e.g. Smith 2001)*

Report IDs of other reports of this study *(e.g. duplicate publications, follow-up studies)*

Notes:

1... General Information

1. **Date form completed** *(dd/mm/~~yyyy~~)*	
2. **Name/ID of person extracting data**	Ac
3. **Report title** *(title of paper/ abstract/ report that data are extracted from)*	
4. **Report ID** *(if there are multiple reports of this study)*	
5. **Reference details**	
6. **Report author contact details**	
7. **Publication type** *(e.g. full report, abstract, letter)*	
8. **Notes:**	

2... Eligibility

Study Characteristics	**Review Inclusion Criteria** *(Insert inclusion criteria for each characteristic as defined in the Protocol)*	**Yes/ No / Unclear**	**Location in text** *(pg & ¶/fig/table)*
9. **Primary text**	Primary report of the study? (long term follow ups can be included but secondary analyses should be excluded)		
10. **Type of study**	Randomised controlled trial		
11. **Participants**	Adults		
12. **Participants**	CFS/ME diagnosed with Oxford or Fukuda criteria/CDC criteria		
13. **Depression**	Recorded at baseline with validated measure		
14. **Anxiety**	Recorded at baseline with validated measure		
15. **Types of intervention**	CBT GET		
16. **Types of outcome measures**	Outcome in CFS/ME symptomology		
17. **Decision:**			
18. **Reason for exclusion**			
19. **Notes:**			

DO NOT PROCEED IF STUDY EXCLUDED FROM REVIEW

3... Population and setting

	Description *Include comparative information for each group (i.e. intervention and controls) if available*
20. **Setting** *(including location and social context)*	
21. **CFS diagnostic criteria**	
22. **Inclusion criteria**	
23. **Exclusion criteria**	
24. **Lower age range specified?**	
25. **Exclusion based on anxiety or depression?**	
26. **Method/s of recruitment of participants**	
27. **Notes:**	

4... Methods

	Descriptions as stated in report/paper
28. **Aim of study**	
29. **Number of treatment arms**	
30. **Dates**	
31. **Duration of participation** *(from recruitment to last follow-up)*	
32. **Notes:**	

5... Risk of Bias assessment

Risk of bias		
Domain	**Risk of bias**	**Support for judgement**
Random sequence generation (selection bias)		
Allocation concealment (selection bias)		
Blinding (performance bias and detection bias) of participants and personnel?		
Blinding (performance bias and detection bias) of outcome assessors?		
Incomplete outcome data (attrition bias) All outcomes		
Selective reporting (reporting bias)		
Other bias		

6... Participants

Provide overall data and, if available, comparative data for each intervention or comparison group.

	Description as stated in report/paper
33. **Total no. randomised** *(or total pop. at start of study for NRCTs)*	
34. **Baseline imbalances**	
35. **Withdrawals and exclusions** *(if not provided below by outcome)*	
36. **Age**	
37. **Sex**	
38. **Race/Ethnicity**	
39. **Severity/duration of illness**	
40. **Co-morbidities**	
41. **Work and employment status**	
42. **Other treatment received** *(additional to study intervention)*	
43. **Other relevant sociodemographics**	
44. **Subgroups measured**	
45. **Subgroups reported**	
46. **Notes:**	

7... Intervention groups

Copy and paste table for each intervention and comparison group

Intervention Group 1

	Description as stated in report/paper
47. **Group name**	
48. **No. randomised to group + number treated**	
49. **Description**	
50. **Duration of treatment period**	
51. **Delivery** *(e.g. mechanism, medium, intensity, fidelity)*	
52. **Manual?**	
53. **No. of sessions**	
54. **Frequency of sessions** *(weekly, fortnightly etc)*	

	Description as stated in report/paper
55. **Length of sessions**	
56. **Providers** *(e.g. no., profession, training, ethnicity etc. if relevant)*	
57. **Supervision?**	
58. **Co-interventions**	
59. **Notes:**	

8... Control groups

Copy and paste table for each control group

Intervention Group 1

	Description as stated in report/paper
60. **Group name**	
61. **No. randomised to group + number treated**	
62. **Description**	
63. **Duration of treatment period**	
64. **Delivery** *(e.g. mechanism, medium, intensity, fidelity)*	
65. **Manual?**	
66. **No. of sessions**	
67. **Frequency of sessions** *(weekly, fortnightly etc)*	
68. **Length of sessions**	
69. **Providers** *(e.g. no., profession, training, ethnicity etc. if relevant)*	
70. **Supervision?**	
71. **Co-interventions**	
72. **Notes:**	

9... Outcomes

73. **List of outcome measures**	
74. **Follow-up times**	

Copy and paste table for each outcome.

Outcome 1 – FATIGUE

	Description as stated in report/paper
75. **Outcome name**	
76. **Time points measured** *(specify whether from start or end of intervention)*	
77. **Time points reported**	
78. **Outcome definition** *(with diagnostic criteria if relevant and note whether the outcome is desirable or undesirable if this is not obvious)*	
79. **Person measuring/ reporting**	
80. **Unit of measurement** *(if relevant)*	
81. **Scales: upper and lower limits** *(indicate whether ~~high or~~ low score is good)*	
82. **Is outcome/tool validated?**	
83. **Imputation of missing data** *(e.g. assumptions made for ITT analysis)*	
84. **Assumed risk estimate** *(e.g. baseline or population risk ~~noted in~~ Background)*	
85. **Notes:**	

Outcome 2 – PHYSICAL FUNCTIONING/QoL

	Description as stated in report/paper
86. **Outcome name**	
87. **Time points measured** *(specify whether from start or end of intervention)*	
88. **Time points reported**	
89. **Outcome definition** *(with diagnostic criteria if relevant and note whether the outcome is desirable or undesirable if this is not obvious)*	
90. **Person measuring/ reporting**	
91. **Unit of measurement** *(if relevant)*	

	Description as stated in report/paper
92. **Scales: upper and lower limits** *(indicate whether high or low score is good)*	
93. **Is outcome/tool validated?**	
94. **Imputation of missing data** *(e.g. assumptions made for ITT analysis)*	
95. **Assumed risk estimate** *(e.g. baseline or population risk noted in Background)*	
96. **Notes:**	

10. Baseline prevalence

	Description as stated in report/paper
97. **Anxiety reported?**	
98. **Anxiety measure**	
99. **Depression reported?**	
100. **Depression measure**	

11. Depression

	Description as stated in report/paper
101. **Measure name**	
102. **Time points reported**	
103. **Person measuring/ reporting**	
104. **Unit of measurement** *(if relevant)*	
105. **Scales: upper and lower limits** *(indicate whether high or low score is good)*	
106. **Is outcome/tool validated?**	
107. **Imputation of missing data** *(e.g. assumptions made for ITT analysis)*	
108. **Assumed risk estimate** *(e.g. baseline or population risk noted in Background)*	
109. **Notes:**	

12. Anxiety

	Description as stated in report/paper
110. **Measure name**	
111. **Time points measured** *(specify whether from start or end of intervention)*	
112. **Time points reported**	
113. **Person measuring/ reporting**	
114. **Unit of measurement** *(if relevant)*	
115. **Scales: upper and lower limits** *(indicate whether high or low score is good)*	
116. **Is outcome/tool validated?**	
117. **Imputation of missing data** *(e.g. assumptions made for ITT analysis)*	
118. **Assumed risk estimate** *(e.g. baseline or population risk noted in Background)*	
119. **Notes:**	

13. Results

Copy and paste the appropriate table for each outcome, including additional tables for each time point and subgroup as required.

For randomised or non-randomised trial - Continuous outcome

	Description as stated in report/paper					
120. **Comparison**						
121. **Outcome**						
122. **Time point** *(specify whether from start or end of intervention)*						
123. **Post-intervention or change from baseline?**						
124. **Results** *Post-treatment, unadjusted*	**Intervention**			**Comparison**		
	Mean	SD (or ~~other~~ variance)	No. participants	Mean	SD (or ~~other~~ variance)	No. participants
125. **6 months follow-up**	**Intervention**			**Comparison**		
	Mean	SD (or ~~other~~ variance)	No. participants	Mean	SD (or ~~other~~ variance)	No. participants
126. **Baseline data**	**Intervention**			**Comparison**		

	Description as stated in report/paper					
	Mean	SD (or ~~other~~ variance)	No. participants	Mean	SD (or ~~other~~ variance)	No. participants
127. **No. missing participants and reasons**						
128. **No. participants moved from other group and reasons**						
129. **Any other results reported**						
130. **Unit of analysis** *(e.g. by individuals, health professional, practice, hospital, community)*						
131. **Statistical methods used and appropriateness of these methods** *(e.g. adjustment for correlation)*						
132. **Reanalysis required?** *(If yes, specify why)*	*Yes/No/Unclear*					
133. **Reanalysis possible?**	*Yes/No/Unclear*					
134. **Reanalysed results**						
135. **Notes:**						

14. Depression/anxiety data

136. **Anxiety BASELINE data**	**Intervention**			**Comparison**		
	Mean	SD (or ~~other~~ variance)	No. participants	Mean	SD (or ~~other~~ variance)	No. participants
137. *Anxiety follow-up data*	*Intervention*			*Comparison*		
	Mean	*SD (or ~~other~~ variance)*	*No. participants*	*Mean*	*SD (or ~~other~~ variance)*	*No. participants*
138. **Depression BASELINE data**	**Intervention**			**Comparison**		
	Mean	SD (or ~~other~~ variance)	No. participants	Mean	SD (or ~~other~~ variance)	No. participants
139. *Depression follow-up data – post-treatment*	*Intervention*			*Comparison*		
	Mean	*SD (or ~~other~~ variance)*		*Mean*	*SD (or ~~other~~ variance)*	
~~6 month~~ follow-up depression data	*Intervention*			*Comparison*		
	Mean	*SD (or ~~other~~ variance)*		*Mean*	*SD (or ~~other~~ variance)*	

140. **No. missing participants and reasons**						
141. **No. participants moved from other group and reasons**						
142. **Any other results reported**						

15. Applicability

143. **Have important populations been excluded from the study?** *(consider disadvantaged populations, and possible differences in the intervention effect)*	*Yes/No/Unclear*	
144. **Is the intervention likely to be aimed at disadvantaged groups?** *(e.g. lower socioeconomic groups)*	*Yes/No/Unclear*	
145. **Does the study directly address the review question?** *(any issues of partial or indirect applicability)*	*Yes/No/Unclear*	
146. **Notes:**		

16. Other information

	Description as stated in report/paper
147. **Key conclusions of study authors**	
148. **References to other relevant studies**	
149. **Correspondence required for further study information** *(what and from whom)*	
150. **Further study information requested** *(from whom, what and when)*	
151. **Correspondence received** *(from whom, what and when)*	
152. **Notes:**	

Service Improvement Project Appendices

Appendix F – Journal of mental health: Instructions for authors

Thank you for choosing to submit your paper to us. These instructions will ensure we have everything required so your paper can move through peer review, production and publication smoothly. Please take the time to read and follow them as closely as possible, as doing so will ensure your paper matches the journal's requirements. For general guidance on the publication process at Taylor & Francis please visit our Author Services website.

This journal uses ScholarOne Manuscripts (previously Manuscript Central) to peer review manuscript submissions. Please read the guide for ScholarOne authors before making a submission. Complete guidelines for preparing and submitting your manuscript to this journal are provided below.

ABOUT THE JOURNAL

Journal of Mental Health is an international, peer-reviewed journal publishing high-quality, original research. Please see the journal's Aims & Scope for information about its focus and peer-review policy.

Please note that this journal only publishes manuscripts in English.

Journal of Mental Health accepts the following types of article: Original Article, Review Article, Research and Evaluation, Book Review and Web Review.

Book Reviews
All books for reviewing should be sent directly to Martin Guha, Book Reviews Editor, Information Services & Systems, Institute of Psychiatry, KCL, De Crespigny Park, PO Box 18, London, SE5 8AF

CONTENTS

Taylor & Francis is committed to peer-review integrity and upholding the highest standards of review. Once your paper has been assessed for suitability by the editor, it will then be double blind peer reviewed by independent, anonymous expert referees. Find out more about what to expect during peer review and read our guidance on publishing ethics.

PREPARING YOUR PAPER

Structure

Your paper should be compiled in the following order: title page; abstract; keywords; main text introduction, materials and methods, results, discussion; acknowledgments; declaration of interest statement; references; appendices (as appropriate); table(s) with caption(s) (on individual pages); figures; figure captions (as a list).

Word Limits

Please include a word count for your paper.

The total word count for Review Articles should be no more than 6000 words. All other articles should be no more than a total of 4000 words. We do not include the abstract, tables and references in this word count. Manuscripts are limited to a maximum of 4 tables and 2 figures.

Style Guidelines

Please refer to these quick style guidelines when preparing your paper, rather than any published articles or a sample copy.

Any spelling style is acceptable so long as it is consistent within the manuscript.

Please use double quotation marks, except where "a quotation is 'within' a quotation". Please note that long quotations should be indented without quotation marks.

Formatting and Templates

Papers may be submitted in Word format. Figures should be saved separately from the text. To assist you in preparing your paper, we provide formatting template(s).

Word templates are available for this journal. Please save the template to your hard drive, ready for use.

If you are not able to use the template via the links (or if you have any other template queries) please contact authortemplate@tandf.co.uk.

References

Please use this reference guide when preparing your paper.

Checklist: What to Include

1. **Author details.** Please include all authors' full names, affiliations, postal addresses, telephone numbers and email addresses on the cover page. Where available, please also include ORCiDs and social media handles (Facebook, Twitter or LinkedIn). One author will need to be identified as the corresponding author, with their email address normally displayed in the article PDF (depending on the journal) and the online article. Authors' affiliations are the affiliations where the research was conducted. If any of the named co-authors moves affiliation during the peer-review process, the new affiliation can be given as a footnote. Please note that no changes to affiliation can be made after your paper is accepted. Read more on authorship.
2. A structured abstract of no more than 200 words. Use the following headings: Background, Aims, Method, Results, Conclusions, Declaration of interest. The declaration of interest should acknowledge all financial support and any financial relationship that may pose a conflict of interest. Acknowledgement of individuals should be confined to those who contributed to the article's intellectual or technical content. Read tips on writing your abstract.
3. You can opt to include a **video abstract** with your article. Find out how these can help your work reach a wider audience, and what to think about when filming.
4. Between 3 and 8 **keywords**. Read making your article more discoverable, including information on choosing a title and search engine optimization.
5. **Funding details.** Please supply all details required by your funding and grant-awarding bodies as follows:
   For single agency grants
   This work was supported by the [Funding Agency] under Grant [number xxxx].
   For multiple agency grants
   This work was supported by the [Funding Agency #1] under Grant [number xxxx]; [Funding Agency #2] under Grant [number xxxx]; and [Funding Agency #3] under Grant [number xxxx].

6. **Disclosure statement.** This is to acknowledge any financial interest or benefit that has arisen from the direct applications of your research. Further guidance on what is a conflict of interest and how to disclose it.
7. **Data availability statement.** If there is a data set associated with the paper, please provide information about where the data supporting the results or analyses presented in the paper can be found. Where applicable, this should include the hyperlink, DOI or other persistent identifier associated with the data set(s). Templates are also available to support authors.
8. **Data deposition.** If you choose to share or make the data underlying the study open, please deposit your data in a recognized data repository prior to or at the time of submission. You will be asked to provide the DOI, pre-reserved DOI, or other persistent identifier for the data set.
9. **Supplemental online material.** Supplemental material can be a video, dataset, fileset, sound file or anything which supports (and is pertinent to) your paper. We publish supplemental material online via Figshare. Find out more about supplemental material and how to submit it with your article.
10. **Figures.** Figures should be high quality (1200 dpi for line art, 600 dpi for grayscale and 300 dpi for colour, at the correct size). Figures should be supplied in one of our preferred file formats: EPS, PS, JPEG, GIF, or Microsoft Word (DOC or DOCX). For information relating to other file types, please consult our Submission of electronic artworkdocument.
11. **Tables.** Tables should present new information rather than duplicating what is in the text. Readers should be able to interpret the table without reference to the text. Please supply editable files.
12. **Equations.** If you are submitting your manuscript as a Word document, please ensure that equations are editable. More information about mathematical symbols and equations.
13. **Units.** Please use SI units (non-italicized).

USING THIRD-PARTY MATERIAL IN YOUR PAPER

You must obtain the necessary permission to reuse third-party material in your article. The use of short extracts of text and some other types of material is usually permitted, on a limited basis, for the purposes of criticism and review without securing formal permission. If you wish to include any material in your paper for which you do not hold copyright, and which is not covered by this informal agreement, you will need to obtain written permission from the copyright owner prior to submission. More information on requesting permission to reproduce work(s) under copyright.

SUBMITTING YOUR PAPER

1. When submitting an Original Article or Research and Evaluation, please include a sentence to confirm that ethical approval has been granted (with the name of the committee and the reference number) and that participants have given consent for their data to be used in the research.
2. When submitting a Review, please confirm that your manuscript is a systematic review and include a statement that researchers have followed the PRISMA

guidance. Please also confirm whether the review protocol has been published on Prospero and provide a date of registration.

This journal uses ScholarOne Manuscripts to manage the peer-review process. If you haven't submitted a paper to this journal before, you will need to create an account in ScholarOne. Please read the guidelines above and then submit your paper in the relevant Author Centre, where you will find user guides and a helpdesk.

Please note that *Journal of Mental Health* uses Crossref™ to screen papers for unoriginal material. By submitting your paper to *Journal of Mental Health* you are agreeing to originality checks during the peer-review and production processes.

On acceptance, we recommend that you keep a copy of your Accepted Manuscript. Find out more about sharing your work.

DATA SHARING POLICY

This journal applies the Taylor & Francis Basic Data Sharing Policy. Authors are encouraged to share or make open the data supporting the results or analyses presented in their paper where this does not violate the protection of human subjects or other valid privacy or security concerns.

Authors are encouraged to deposit the dataset(s) in a recognized data repository that can mint a persistent digital identifier, preferably a digital object identifier (DOI) and recognizes a long-term preservation plan. If you are uncertain about where to deposit your data, please see this information regarding repositories.

Authors are further encouraged to cite any data sets referenced in the article and provide a Data Availability Statement.

At the point of submission, you will be asked if there is a data set associated with the paper. If you reply yes, you will be asked to provide the DOI, pre-registered DOI, hyperlink, or other persistent identifier associated with the data set(s). If you have selected to provide a pre-registered DOI, please be prepared to share the reviewer URL associated with your data deposit, upon request by reviewers.

Where one or multiple data sets are associated with a manuscript, these are not formally peer reviewed as a part of the journal submission process. It is the author's responsibility to ensure the soundness of data. Any errors in the data rest solely with the producers of the data set(s).

PUBLICATION CHARGES

There are no submission fees or page charges for this journal.

Colour figures will be reproduced in colour in your online article free of charge. If it is necessary for the figures to be reproduced in colour in the print version, a charge will apply.

Charges for colour figures in print are £300 per figure ($400 US Dollars; $500 Australian Dollars; €350). For more than 4 colour figures, figures 5 and above will be charged at £50 per figure ($75 US Dollars; $100 Australian Dollars; €65). Depending on your location, these charges may be subject to local taxes.

COPYRIGHT OPTIONS

Copyright allows you to protect your original material, and stop others from using your work without your permission. Taylor & Francis offers a number of different license and reuse options, including Creative Commons licenses when publishing open access. Read more on publishing agreements.

COMPLYING WITH FUNDING AGENCIES

We will deposit all National Institutes of Health or Wellcome Trust-funded papers into PubMedCentral on behalf of authors, meeting the requirements of their respective open access policies. If this applies to you, please tell our production team when you receive your article proofs, so we can do this for you. Check funders' open access policy mandates here. Find out more about sharing your work.

OPEN ACCESS

This journal gives authors the option to publish open access via our Open Select publishing program, making it free to access online immediately on publication. Many funders mandate publishing your research open access; you can check open access funder policies and mandates here.

Taylor & Francis Open Select gives you, your institution or funder the option of paying an article publishing charge (APC) to make an article open access. Please contact openaccess@tandf.co.uk if you would like to find out more, or go to our Author Services website.

For more information on license options, embargo periods and APCs for this journal please go here.

MY AUTHORED WORKS

On publication, you will be able to view, download and check your article's metrics (downloads, citations and Altmetric data) via My Authored Works on Taylor & Francis Online. This is where you can access every article you have published with us, as well as your free eprints link, so you can quickly and easily share your work with friends and colleagues.

We are committed to promoting and increasing the visibility of your article. Here are some tips and ideas on how you can work with us to promote your research.

ARTICLE REPRINTS

You will be sent a link to order article reprints via your account in our production system. For enquiries about reprints, please contact the Taylor & Francis Author Services team at reprints@tandf.co.uk. You can also order print copies of the journal issue in which your article appears.

QUERIES

Should you have any queries, please visit our Author Services website or contact us at authorqueries@tandf.co.uk.

Updated 16-01-2018

Appendix G: Trust confirmation of service evaluation approval

Avon and Wiltshire NHS
Mental Health Partnership NHS Trust

Avon and Wiltshire Mental Health Partnership AWP Trust
AWP Quality Academy
Fromeside- East Wing
Manor Road
Fishponds
BS16 2EW

0117 378 4217

Date: 17th February 2017

Dear Amy,

Evaluating the use of the "My Wellbeing Toolkit''
AWP Reference: E002.2017 Caswell

This letter is to confirm that your evaluation is now approved and also provides you with our reference number.

If you do need any further support or information, please contact us using the contact details above, quoting our reference number for your study.

The importance of disseminating all evaluation work cannot be over emphasised. It is only by sharing our learning that we can improve services across AWP. For this reason, the findings of all evaluation work should be reported to the Evaluation team via email. The team will champion the results of service evaluations, and work with evaluators to ensure those results are disseminated and acted upon, and that the results of evaluations are reflected in future service delivery. The team will also work with evaluators to produce publications for the public domain.

Furthermore, please remember that this project is service evaluation, not research. Therefore, it should not be represented as research in the future through publications or other reporting.

I very much look forward to receiving the results of your evaluation in due course.

Yours sincerely,
Bryony McCann

Appendix H: Trust confirmation of amendment to service evaluation

Avon and Wiltshire NHS
Mental Health Partnership NHS Trust

Avon and Wiltshire Mental Health Partnership AWP Trust
AWP Quality Academy
Fromeside- East Wing
Manor Road
Fishponds
BS16 2EW

0117 378 4217

Date: 11th May 2017

Dear Amy,

Evaluating the use of the "My Wellbeing Toolkit''
AWP Reference: 2017.E002 Caswell

This letter is to confirm that your amended evaluation is now approved and also provides you with our reference number.

If you do need any further support or information, please contact us using the contact details above, quoting our reference number for your study.

The importance of disseminating all evaluation work cannot be over emphasised. It is only by sharing our learning that we can improve services across AWP. For this reason, the findings of all evaluation work should be reported to the Evaluation team via email. The team will champion the results of service evaluations, and work with evaluators to ensure those results are disseminated and acted upon, and that the results of evaluations are reflected in future service delivery. The team will also work with evaluators to produce publications for the public domain.

I very much look forward to receiving the results of your evaluation in due course.

Yours sincerely,

Bryony McCann

Appendix I: University confirmation of ethical approval

Dear Amy,

I am happy to confirm that you now have full ethical approval from the University of Bath Psychology Ethics Committee.

Please use the code 17-007 for all internal purposes.

Best of luck with your research,

Dr. Nathalia Gjersoe

Chair, Psychology Ethics Committee

Appendix J: Participant Information Sheet

Avon and Wiltshire NHS
Mental Health Partnership NHS Trust

Evaluation of the "My Wellbeing Toolkit" booklet

Participant Information Sheet

17 February 2017

We'd like to invite you to take part in our service evaluation project. Joining the project is entirely up to you. Before you decide, we would like you to understand why the service evaluation is being done and what it would involve for you.

The project will evaluate the "My Wellbeing Toolkit" booklet. It will look at whether you used the booklet, whether you found it helpful, how it could be improved and what made using the booklet difficult.

The project will involve a short questionnaire about your experiences of the booklet and a subset of participants will be invited to participate in a focus group about the booklet. You can participate if you are a care coordinator in the recovery team.

Please read the following information carefully and contact me if there is anything that is not clear, or if you would like more information.

Details of the project

Why are we doing the project?

The purpose of the project is to evaluate the My Wellbeing Toolkit that is available for use in the Recovery Team.

The project will ask the following questions:

1. Have care coordinators been using the "My Wellbeing Toolkit" booklet with clients?
2. What have been the barriers and facilitators to using the booklet?
3. In what ways has using the booklet improved client sessions?
4. In what ways could the booklet be improved?

We are doing this service evaluation so that we can improve the booklet for you. The evaluation will mean that the booklet is fit for purpose which will make your role easier. We want to create guidelines to make using the booklet easier for you and we also want to write a second edition of the booklet in the future. By participating in the evaluation you will help tell us how the booklet can be used and improved.

What would taking part involve?

The evaluation has two parts: a questionnaire and a focus group.

First, a brief, anonymous, questionnaire will ask about your experience of using the booklet. The questionnaire will take up to 15 minutes to complete and you will only complete it once. You can complete it during working hours, or outside of work.

After this, a small subset of care coordinators (8-10 people) will be invited to participate in the focus group. The focus group includes questions about how often

you used the booklet, the barriers and facilitators you have experienced to using the booklet, how useful you found it, and what ways you think it could be improved. The focus group will last approximately 45 minutes – 1 hour. The focus group will be audio recorded.

You do not need to have used the booklet to participate in either the questionnaire or the focus group as we are also interested in the responses of people who haven't used it.

Who can participate? We are inviting all the care-coordinators in the Recovery Team to complete the questionnaire. You can participate even if you have not used the booklet.

Where will the project take place? The project will take place at NHS House.

Who is involved in the service evaluation:

- Amy Caswell - Trainee Clinical Psychologist, University of Bath – Main researcher
- Dr Emma Griffith - Clinical Psychologist, AWP, and Clinical Tutor at Bath University
- Dr Chris Gillmore – Clinical Psychologist, AWP
- Dr Hanna van der Woude – Clinical Psychologist, AWP

The NHS and the University of Bath have reviewed the protocol of this study, and have given ethical approval for it.

What are the possible benefits of taking part?

We are doing this service evaluation so that we can improve the booklet. This will mean that any future editions of the booklet are improved.

Participating in the evaluation will mean that you are taking an active role in shaping services. It means you will contribute to guiding the resources you have available to you.

What are the possible disadvantages and risks of taking part?

We have been careful to minimise any possible disadvantages or risks to you. Your responses on the questionnaire and focus group will be anonymous, and participation is entirely up to you. Please see sections below for further information about this.

Further supporting information

Do I have to participate? As you have been asked to do this in a professional capacity, you may feel pressure to take part in the project or to remain part of it once it starts. You are not required to participate, and can choose to withdraw your participation at any point during the study. Your decision to participate or not participate in the service evaluation will not in any way affect your employment. The names of care coordinators who have chosen not to participate will not be made available to management.

What will happen if you don't want to carry on with the project? If you start completing the questionnaire and decide you don't want to continue, you can simply

not submit the questionnaire the researcher. Once you have submitted a questionnaire to the researcher, this data will be anonymous and you will no longer be able to withdraw your responses.

If you start completing the focus group and decide you don't want to continue you can leave the group and withdraw your responses. You will have 2 weeks after the focus group to withdraw your responses should you change your mind about participating. After 2 weeks you will no longer be able to withdraw as your responses will have been transcribed anonymously.

Are my responses anonymous and confidential? Consent forms and questionnaires will be stored separately in a locked filing cabinet. Managers will not receive feedback about your responses and will not be told as to whether you used the booklet or not.

Please be assured that questionnaire data is anonymous. You will not write your name anywhere on your questionnaire.

The focus group will be audio-recorded. Your responses during the focus group will also be anonymised. Two weeks after the completion of the focus group, the recording will be transcribed. At this point, names and identifying information will be removed from the transcript. After this, the original audio recording will be destroyed.

What will happen to the responses I give? The responses you give will be collated with those submitted by other care-coordinators.

The raw data will be initially analysed by me. The final analysis will be conducted by me in consultation with the other researchers involved in the study, and will not include the names of any participants.

What will happen to the findings from the evaluation project? The results of the evaluation will be sent to all care coordinators who participated in the study, as well as the Therapies Team and the Recovery Team. Versions of the results will also be submitted for publication to journals and presentation at conferences deemed appropriate. Please be assured that your name will not be identifiable in any version of results submitted for publication or presentation.

What if I have concerns about the project? If you have any concerns about the evaluation please contact the researcher, Amy Caswell a.caswell@bath.ac.uk, or the primary supervisor Dr Emma Griffith e.j.griffith@bath.ac.uk.

Further questions

Please contact me if you have any further questions about the service evaluation, or would like additional information: a.caswell@bath.ac.uk

Thank you for your time taken to read this sheet and consider taking part in this project.

Amy Caswell

Clinical Psychologist in Training, University of Bath

Appendix K: Questionnaire consent form

Avon and Wiltshire NHS
Mental Health Partnership NHS Trust

Evaluation of the "My Well-being Toolkit" booklet

Consent Form to participate

CONFIDENTIAL

Title of project: Evaluation of the "My Well-being Toolkit" booklet

Name of Researcher: Dr Amy Caswell

	Please circl
I confirm that I have read the information sheet dated 17 February 2017 for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	Yes / No
I understand that my participation is voluntary and that I am free to withdraw at any time during the study without giving any reason.	Yes / No
I understand that my responses will be kept anonymously	Yes / No
Do you agree to take part in completing the questionnaire?	Yes / No
Do you agree to be contacted about completing the focus group?	Yes / No

Signed …… Date……/……/20……..

Name in Block Letters ……...

Signature of investigator …….. Date……/……/20……..

Appendix L: Focus group consent form

Evaluation of the "My Wellbeing Toolkit" booklet

Consent Form to participate in the focus group

CONFIDENTIAL

Title of project: Evaluation of the "My Wellbeing Toolkit" booklet

Name of Researcher: Dr Amy Caswell

	Please circl
I confirm that I have read the information sheet dated 17 February 2017 for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	Yes / No
I understand that my participation is voluntary and that I am free to withdraw at any time during the focus group, and up to two weeks after, without giving any reason.	Yes / No
I understand that my responses will be kept anonymously	Yes / No
Do you agree to take part in completing the focus group?	Yes / No

Signed …… Date……/…… /20……..

Name in Block Letters ……..……..

Signature of investigator …….. Date……/…… /20……..

Appendix M: Questionnaire

Evaluating the use of the "My Well-being Toolkit"

Questionnaire

Thank you for agreeing to complete the questionnaire evaluating the "My Well-being Toolkit"

Please answer the following questions as accurately as possible. Your answers are anonymous.

If you have used the booklet with clients, or have read it, please complete all sections

SECTION 1:

1) **Have you used the "My Well-being" Toolkit in your sessions with clients?**

   ☐ Yes

   ☐ No ***(please proceed to question 5)***

2) **How many clients have you used the "My Well-being Toolkit" with?**

   ☐ All of my clients

   ☐ Some of my clients

Please provide approximate number of clients you have used the booklet with

_____

3) **How frequently do you use the booklet on average with clients?**

   ☐ Every session

   ☐ Most sessions

   ☐ About half of the time

   ☐ Occasionally

   ☐ Rarely

   ☐ Just once

4) **When you use the booklet, how much of the session do you use it for?**

- ☐ All of the session
- ☐ Most of the session
- ☐ Some of the session
- ☐ A little of the session

5) When you have not used the booklet with clients, why not? *(select as many as appropriate)*

- ☐ It hasn't been suitable for a client
- ☐ Client has not wanted to use it
- ☐ I have not felt confident using it
- ☐ I don't find it useful
- ☐ Other *(please provide details)*

_____
_____
_____

6) When you haven't used it with clients, have you suggested using it to them? *(select as many as appropriate)*

- ☐ Yes but they have not wanted to
- ☐ Yes but it hasn't been suitable for the work
- ☐ No
- ☐ Other *(please provide details)*

_____
_____
_____

7) What have been the barriers you've experienced to using the booklet?

_____
_____
_____
_____
_____
_____

How could these barriers be addressed?

_____
_____
_____
_____
_____
_____

8) What has made using the booklet easier?

_____
_____
_____
_____
_____
_____

Could this be improved in any way?

_____
_____
_____
_____
_____
_____

SECTION 2:

USEFULNESS OF THE BOOKLET

Please only answer the following questions if you have used the booklet with

1) Overall, have you found the booklet helpful/useful?

☐ Yes *(please provide details)*

_____
_____
_____

☐ No *(please provide details)*

_____
_____
_____

2) Did the booklet help provide structure to sessions?

☐ Yes, a lot

☐ A little

☐ No

Any additional comments:

_____
_____
_____

3) Did the booklet help develop a shared understanding with clients?

☐ Yes, a lot

☐ A little

☐ No
Any additional comments:
_____
_____
_____

4) Did the booklet promote discussion around recovery?

☐ Yes, a lot

☐ A little

☐ No
Any additional comments:
_____
_____
_____

5) Did the booklet facilitate psychological discussion?

☐ Yes, a lot

☐ A little

☐ No
Any additional comments:
_____
_____
_____

6) Did the booklet aid discussion of goals and priorities?

☐ Yes, a lot

☐ A little

☐ No
Any additional comments:
_____
_____
_____

7) Would you recommend the booklet to another clinician or care-coordinator?

☐ Yes

☐ No
Any additional comments:

_____
_____
_____

8) Would you recommend the booklet to a client?

☐ Yes

☐ No

Any additional comments:

_____
_____
_____

SECTION 3:

IMPROVING THE BOOKLET

9) What would you like to stay the same about the booklet?

_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

10) How could the booklet be improved?

_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

Appendix N: Focus group schedule

Focus group schedule

The focus group will cover four primary areas: (1) evaluating in what ways the booklet was helpful (2) evaluating times when the booklet was not used (3) Identifying barriers and facilitators to use (4) Identifying areas in which the booklet can be improved.

Example questions are provided below. These will not be prescriptive, although will be used as prompts to keep participants on track if necessary.

Evaluating how the booklet was helpful:

1. **How much did you use the booklet?**
2. **In what ways did you find the wellbeing toolkit helpful? What was good about it?**
   Prompt if needed:
   a. Did it help provide structure to sessions?
   b. Did it help develop a shared understanding?
   c. Did it help someone move along their recovery? This might include developing hope, relationships, empowerment, discovering meaning.
   d. Did it facilitate psychological discussion?
   e. Did it aid discussion of goals and priorities?
3. Which sections did you find most helpful? (NB a copy of the booklet will be available to look through if needed).
4. When working with a client, what contributed to you deciding to use the booklet?

Evaluating times when the booklet was not used:

5. **Were there times when you didn't use the booklet?**
   a. If yes, why not?

Identifying barriers and facilitators to use:

6. **Was there anything that got in the way of using the booklet?**
   a. Is there anything that could be put into place to help with this?
   b. Did the booklet come up in supervision?
   c. Has this felt like a priority?
   d. Does it feel like the organisation is supporting use of materials like this?

7. **What made using the booklet easier/what facilitated using the booklet?**
   a. Is there anything that could be put into place to help with this?

Now I want to think about whether we should change the booklet:

8. **In what ways do you think the booklet could be improved?**
   Prompt if needed:
   a. Are there any sections that could be changed?
   b. How could it be made easier to implement?
9. In what ways should we keep the booklet the same?

Now any final thoughts?

Appendix O: Summary sheet

The "My Wellbeing Toolkit": A Service Improvement Project

Amy Caswell, Clinical Psychologist in Training, University of Bath

Background:

The "My Wellbeing Toolkit" is a mind map based booklet, designed for use in secondary care mental health services by Hanna van der Woude, Clinical Psychologist.

Mind map booklets have been used extensively in substance misuse support services, however have not been previously trialled within secondary care mental health services.

The current service improvement project

The current service improvement project was commissioned to make recommendations for improvements to the booklet.

The project was split into two stages:

1. Establish clinician experiences of using the booklet
    a. Have Recovery Service care coordinators been routinely using the booklet with clients?
    b. Have care coordinators found the booklet helpful? If so, in what way?
    c. What have been the barriers and facilitators to using the booklet?
    d. How do care coordinators think use of the booklet be supported and improved?
2. Make recommendations, as necessary, for improvement

Methods:

Care coordinators in the BaNES Recovery Service were invited to participate in a questionnaire and focus group exploring experiences of using the booklet.

Results:

10 care coordinators completed the questionnaire; 7 completed the focus group

Overall. care coordinators found the booklet very useful in their work. They reported that the booklet was very useful for themselves and for clients:

"Some of the people that I've given this to with personality disorder have actually found it very helpful"

"It's something they can look at and work on, and it's very much their thing"

"to learn some coping strategies and understand what their strengths and weaknesses are, it's really useful"

"I did this… as an ability to try to get to know them…. and getting to know their insight into their life, really"

"It's just nice having it all in one booklet"

"It's also a nice thing as part of the discharge…. and potentially, there's a sharing possibility [with other professionals]"

However, care coordinators reported that there were some barriers that got in the way of using the booklet:
1. Practical barriers 2. Lack of clarity and confidence over using the booklet 3. Lack of client engagement

Improvements:

Care coordinators liked the content, layout and design of the booklet, and thought it was user friendly. They suggested a number of areas for improvement:

1. Extra information about online/email/text support services, for self-harm and mental health difficulties.
2. Information on the role of attachment in difficulties
3. Information on the experience of hearing voices
4. A page to record contact details of professionals

It was suggested that the booklet could be developed into an electronic app or pocket sized version.
There was also a suggestion that changing the booklet to a folder would make it easier to log progress

RECOMMENDATIONS

The above changes are recommended to improve the content of the booklet. In addition, the following improvements are recommended:

1. Address practical barriers to use by providing the booklets in all new starter packs, and leaving booklets in an accessible location
2. Hold training sessions and workshops to develop care coordinator confidence using the booklet
3. Commission an additional service improvement project to gather client feedback on the booklet
4. Consider developing a second edition of the booklet, containing additional content.
5. Consider development of an electronic app,

Main Research Project Appendices

Appendix P – Journal guidelines (Psycho-oncology)

1. SUBMISSION

Thank you for your interest in *Psycho-Oncology*. Note that submission implies that the content has not been published or submitted for publication elsewhere except as a brief abstract in the proceedings of a scientific meeting or symposium.

Once you have prepared your submission in accordance with the Guidelines, manuscripts should be submitted online at https://mc.manuscriptcentral.com/pon

The submission system will prompt you to use an ORCiD (a unique author identifier) to help distinguish your work from that of other researchers. Click here to find out more.

Click here for more details on how to use ScholarOne.

For help with submissions, please contact Psycho-Oncology@wiley.com

We look forward to your submission.

2. AIMS AND SCOPE

Psycho-Oncology is concerned with the psychological, social, behavioral, and ethical aspects of cancer. This sub-speciality addresses the two major psychological dimensions of cancer: the psychological responses of patients to cancer at all stages of the disease, and that of their families and caretakers; and the psychological, behavioral and social factors that may influence the disease process. Psycho-oncology is an area of multi-disciplinary interest and has boundaries with the major specialities in oncology: the clinical disciplines (surgery, medicine, pediatrics, radiotherapy), epidemiology, immunology, endocrinology, biology, pathology, bioethics, palliative care, rehabilitation medicine, clinical trials research and decision making, as well as psychiatry and psychology.

This international journal is published twelve times a year and will consider contributions to research of clinical and theoretical interest. Topics covered are wide-ranging and relate to the psychosocial aspects of cancer and AIDS-related tumors, including: epidemiology, quality of life, palliative and supportive care, psychiatry, psychology, sociology, social work, nursing and educational issues.

Special reviews are offered from time to time. Summary proceedings of important national and international symposia falling within the aims of the journal are presented.

Manuscripts should be confined to work relating to cancer and AIDS-related tumors. The criteria for publication are originality, high scholarly quality as determined by peer review, interest to a wide audience of those concerned with psycho-oncology.

3. MANUSCRIPT CATEGORIES AND REQUIREMENTS

Psycho-Oncology publishes a number of different article types including:

• **Original Paper**
Original research papers should contain reports of new research findings that make a significant contribution to knowledge. Original papers should not exceed 4,000 words (including no more than four figures and/or tables) plus up to 40 references.

• **Reviews**
Reviews should be critical reviews of the literature, including systematic reviews and meta-analyses and should not exceed 6,000 words, excluding references. Please complete and upload a PRISMA or AMSTAR checklist for systematic reviews.

• **Invited Editorials and Commentaries**
Please approach the Editorial Office (Psycho-Oncology@wiley.com) for details.

• **Clinical Correspondence**
This includes brief commentaries, letters to the editor, feasibility studies, clinical updates, case reports and brief research reports. They must include five succinct key points (and no abstract), not exceed 1,500 words in total (including no more than two figures/tables). References should be limited to ten and are not included in the word count.

• **Obituaries**

• **Registered Reports**
Psycho-Oncology is offering authors a new article type designed to increase the transparency and reproducibility of hypothesis-driven science, the Registered Report. Registered Reports differ from conventional research article as part of the review process is conducted *before* authors collect and analyse data. The cornerstone of the Registered Reports format is that a significant part of the

manuscript will be assessed prior to data collection, with the highest quality submissions accepted in advance. Please view the full Registered Reports author guidelines here to help prepare your submission.

Qualitative manuscript submissions should usually be based on a minimum of 20 respondents. Authors may contact the Editor (maggie.watson@live.co.uk) if they require further details.

For cross sectional studies, we require authors to adhere to the STROBE reporting standards for observational research. Please upload your STROBE checklist alongside your submission.

4. PREPARING YOUR SUBMISSION

Manuscripts must be submitted as a Word or rtf file and should be written in English. The manuscript should be submitted in separate files: main text file; figures.

Text file

The text file should be presented in the following order:

(i) Title; (ii) a short running title of less than 70 characters; (iii) the full names of the authors; (iv) the author's institutional affiliations at which the work was carried out, (footnote for author's present address if different to where the work was carried out); (v) abstract; (vi) main text, (vii) acknowledgements, (viii) conflict of interest statement, (ix) references, (x) tables (each table complete with title and footnotes) (xi) figure legends, (xii) appendices (if relevant). Figures and supporting information should be supplied as separate files.

Title

The title should be a short informative title that contains the major key words. The title should not contain abbreviations (see Wiley's best practice SEO tips)

Authorship

Please refer to the journal's authorship policy the Editorial Policies and Ethical Considerations section for details on eligibility for author listing.

Acknowledgements

Contributions from anyone who does not meet the criteria for authorship should be listed, with permission from the contributor, in an Acknowledgments section. Financial and material support should also be mentioned. Thanks to anonymous reviewers are not appropriate.

Conflict of Interest Statement

You will be asked to disclose conflicts of interest during the submission process. See the section 'Conflict of Interest' in the Editorial Policies and Ethical Considerations section for details on what to include in this section. Please ensure that you liaise with all co-authors to confirm agreement with the final statement. The Conflict of Interest statement should be included within the main text file of your submission.

Abstract

Please provide an abstract of no more than 250 words. Abstracts should be structured according to the following headings: objective, methods, results, conclusions.

Keywords

Please provide up to 10 keywords and list them in alphabetical order. Please ensure that the keywords, cancer and oncology, are used for indexing purposes. Keywords should be taken from those recommended by the US National Library of Medicine's Medical Subject Headings (MeSH) browser list at https://www.nlm.nih.gov/mesh/.

Main text

Where possible, the text should be divided into the following sections: Background, Methods (including statistical methods), Results and Conclusions. All papers must include within the Conclusions section a paragraph explaining the study limitations (with subtitle "study limitations") and a paragraph explaining the clinical implications of the study (with subtitle "clinical implications").

A statement explicitly describing the ethical background to this study and any institutional or national ethical committee approval (including approval number) must be included within the manuscript.

For clinical trial reports, the clinical trial registration number must be included within the manuscript.

References

All references should be numbered consecutively in order of appearance and should be as complete as possible. In text citations should be superscript numbers. Journal titles are abbreviated; abbreviations may be found in the following: MEDLINE, Index Medicus, or CalTech Library.

Submissions are not required to reflect the precise reference formatting of the journal (use of italics, bold etc.), however it is important that all key elements of each reference are included. Please see below for examples of reference content requirements.

For more information, please see the Vancouver Reference Style Guide

Sample references follow:

Journal Article

1. Wood WG, Eckert GP, Igbavboa U, Muller WE. Statins and neuroprotection: a prescription to move the field forward. Ann N Y Acad Sci 2010; 1199:69-76.

Book

2. Hoppert, M. Microscopic techniques in biotechnology. Weinheim: Wiley-VCH; 2003.

Electronic Material

3. Cancer-Pain.org [homepage on the internet]. New York: Association of Cancer Online Resources, Inc.; c2000–01 [Cited 2015 May 11]. Available from: http://www.cancer-pain.org/.

Tables

Tables should be self-contained and complement, but not duplicate, information contained in the text. They should be supplied as editable files, not pasted as images. Legends should be concise but comprehensive – the table, legend and footnotes must be understandable without reference to the text. All abbreviations must be defined in footnotes. Footnote symbols: †, ‡, §, ¶, should be used (in that order) and *, **, *** should be reserved for P-values. Statistical measures such as SD or SEM should be identified in the headings.

Figure Legends

Legends should be concise but comprehensive – the figure and its legend must be understandable without reference to the text. Include definitions of any symbols used and define/explain all abbreviations and units of measurement.

Preparing Figures

Although we encourage authors to send us the highest-quality figures possible, for peer-review purposes we are happy to accept a wide variety of formats, sizes, and resolutions.

Click here for the basic figure requirements for figures submitted with manuscripts for initial peer review, as well as the more detailed post-acceptance figure requirements.

Guidelines for Cover Submissions

If you would like to send suggestions for artwork related to your manuscript to be considered to appear on the cover of the journal, please follow these general guidelines.

Appendices

Appendices will be published after the references. For submission they should be supplied as separate files but referred to in the text. Supporting Information

Supporting Information

Supporting information is information that is not essential to the article but that provides greater depth and background. It is hosted online, and appears without editing or typesetting. It may include tables, figures, videos, datasets, etc. Click here for Wiley's FAQs on supporting information.

Note, if data, scripts or other artefacts used to generate the analyses presented in the paper are available via a publicly available data repository, authors should include a reference to the location of the material within their paper.

General Style Points

The following links provide general advice on formatting and style.

• Abbreviations: In general, terms should not be abbreviated unless they are used repeatedly and the abbreviation is helpful to the reader. Initially use the word in full, followed by the abbreviation in parentheses. Thereafter use the abbreviation only.
• Units of measurement: Measurements should be given in SI or SI-derived units. Visit the Bureau International des Poids et Mesures (BIPM) website at http://www.bipm.fr for more information about

SI units.
• Trade Names: Chemical substances should be referred to by the generic name only. Trade names should not be used. Drugs should be referred to by their generic names. If proprietary drugs have been used in the study, refer to these by their generic name, mentioning the proprietary name, and the name and location of the manufacturer, in parentheses.

Wiley Author Resources

Wiley has a range of resources for authors preparing manuscripts for submission available here. In particular, authors may benefit from referring to Wiley's best practice tips on Writing for Search Engine Optimization.

Editing, Translation and Formatting Support: Wiley Editing Services can greatly improve the chances of your manuscript being accepted. Offering expert help in English language editing, translation, manuscript formatting and figure preparation, Wiley Editing Services ensures that your manuscript is ready for submission.

5. EDITORIAL POLICIES AND ETHICAL CONSIDERATIONS

Editorial Review and Acceptance

The acceptance criteria for all papers is the quality and originality of the research and its significance to our readership. Except where otherwise stated, manuscripts are single-blind peer reviewed. Papers will only be sent to review if the Editors determine that the paper meets the appropriate quality and relevance requirements. Wiley's policy on confidentiality of the review process is available here.

Appeal of Decision

Authors who wish to appeal the decision on their manuscript may do so by emailing the Editor within 28 days of notification of the decision. In such cases, a letter detailing the reasons for appeal as well as a full response to any reviewers' comments, if relevant, should be provided to the Editor. If appropriate, the manuscript will be sent to another reviewer who has not previously evaluated the manuscript. The reviewers' comments, along with any subsequent editorial communications, will be assessed by the Editor. The Editor's decision will be final.

Manuscript Transfer Programme

Psycho-Oncology collaborates with Wiley's open access journal Cancer Medicine, to enable rapid publication of good quality research that we are unable to accept for publication in Psycho-Oncology. Authors will be offered the option of having the paper, along with any related peer reviews, automatically transferred for consideration by the Editor of Cancer Medicine. Authors will not need to reformat or rewrite their manuscript at this stage, and publication decisions will be made a short time after the transfer takes place. The Editor of Cancer Medicine will accept submissions that report well-conducted research which reaches the standard acceptable for publication. Cancer Medicine is a Wiley Open Access journal and article publication fees apply. For further information, see the cancer medicine website.

Data Sharing and Accessibility

The journal encourages authors to share the data and other artefacts supporting the results in the paper by archiving it in an appropriate public repository. Authors should include a data accessibility statement, including a link to the repository they have used, in order that this statement can be published alongside their paper.

Ethics

A statement explicitly describing the ethical background to this study and any institutional or national ethical committee approval must be included within the manuscript.

Human Studies and Subjects

For manuscripts reporting medical studies involving human participants, we require a statement identifying the ethics committee that approved the study, and that the study conforms to recognized standards, for example: Declaration of Helsinki; US Federal Policy for the Protection of Human Subjects; or European Medicines Agency Guidelines for Good Clinical Practice.

Images and information from individual participants will only be published where the authors have obtained the individual's prior written informed consent. Authors should note in their methods section that informed written consent was obtained. Authors do not need to provide a copy of the consent form to the publisher during submission. However, in signing the author license to publish, authors are required to confirm that consent has been obtained. The Journal reserves the right to request proof of written consent at any time. Wiley has a standard patient consent form available.

Clinical Trial Registration

We require that clinical trials are prospectively registered in a publicly accessible database and clinical trial registration numbers should be included in all papers that report their results. Please include the name of the trial register and your clinical trial registration number at the end of your abstract. If your trial is not registered, or was registered retrospectively, please explain the reasons for this.

Research Reporting Guidelines

Accurate and complete reporting enables readers to fully appraise research, replicate it, and use it. We encourage authors to adhere to the following research reporting standards.

• CONSORT
• SPIRIT
• PRISMA
• PRISMA-P
• STROBE
• CARE
• COREQ
• STARD and TRIPOD
• CHEERS
• the EQUATOR Network
• Future of Research Communications and e-Scholarship (FORCE11)
• ARRIVE guidelines • National Research Council's Institute for Laboratory Animal Research guidelines: the Gold Standard Publication Checklist from Hooijmans and colleagues
• Minimum Information Guidelines from Diverse Bioscience Communities (MIBBI) website; Biosharing website
• REFLECT statement

Genetic Nomenclature

Sequence variants should be described in the text and tables using both DNA and protein designations whenever appropriate. Sequence variant nomenclature must follow the current HGVS guidelines; see http://varnomen.hgvs.org/, where examples of acceptable nomenclature are provided.

Conflict of Interest

Psycho-Oncology requires that all authors disclose any potential sources of conflict of interest. Any interest or relationship, financial or otherwise that might be perceived as influencing an author's objectivity is considered a potential source of conflict of interest. These must be disclosed when directly relevant or directly related to the work that the authors describe in their manuscript. Potential sources of conflict of interest include, but are not limited to, patent or stock ownership, membership of a company board of directors, membership of an advisory board or committee for a company, and consultancy for or receipt of speaker's fees from a company. The existence of a conflict of interest does not preclude publication. If the authors have no conflict of interest to declare, they must also state this at submission. It is the responsibility of the corresponding author to review this policy with all authors and collectively to disclose with the submission ALL pertinent commercial and other relationships. The Conflict of Interest statement should be included within the main text file of your submission.

Funding

Authors should list all funding sources in the Acknowledgments section. Authors are responsible for the accuracy of their funder designation. If in doubt, please check the Open Funder Registry for the correct nomenclature: http://www.crossref.org/fundingdata/registry.html

Authorship

The list of authors should accurately illustrate who contributed to the work and how. All those listed as authors should qualify for authorship according to the following criteria:

1) Have made substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data;

2) Been involved in drafting the manuscript or revising it critically for important intellectual content;

3) Given final approval of the version to be published. Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content; and

4) Agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Contributions from anyone who does not meet the criteria for authorship should be listed, with permission from the contributor, in an Acknowledgments section (for example, to recognize contributions from people who provided technical help, collation of data, writing assistance, acquisition of funding, or a department chairperson who provided general support). Prior to submitting the article all authors should agree on the order in which their names will be listed in the manuscript.

Additional authorship options

Joint first or senior authorship: In the case of joint first authorship a footnote should be added to the author listing, e.g. 'X and Y should be considered joint first author' or 'X and Y should be considered joint senior author.'

ORCID

As part of our commitment to supporting authors at every step of the publishing process, *Psycho-Oncology* requires the submitting author (only) to provide an ORCID iD when submitting a manuscript. This takes around 2 minutes to complete. Find more information here.

Publication Ethics

Psycho-Oncology is a member of the Committee on Publication Ethics (COPE). Note this journal uses iThenticate's CrossCheck software to detect instances of overlapping and similar text in submitted manuscripts. Read our Top 10 Publishing Ethics Tips for Authors here. Wiley's Publication Ethics Guidelines can be found at https://authorservices.wiley.com/ethics-guidelines/index.html

6. AUTHOR LICENSING

If your paper is accepted, the author identified as the formal corresponding author will receive an email prompting them to log in to Author Services, where via the Wiley Author Licensing Service (WALS) they will be required to complete a copyright license agreement on behalf of all authors of the paper.

Authors may choose to publish under the terms of the journal's standard copyright agreement, or OnlineOpen under the terms of a Creative Commons License.

General information regarding licensing and copyright is available here. To review the Creative Commons License options offered under OnlineOpen, please click here. (Note that certain funders mandate that a particular type of CC license has to be used; to check this please click here.)

Self-Archiving definitions and policies. Note that the journal's standard copyright agreement allows for self-archiving of different versions of the article under specific conditions. Please click here for more detailed information about self-archiving definitions and policies.

Open Access fees: If you choose to publish using OnlineOpen you will be charged a fee. A list of Article Publication Charges for Wiley journals is available here.

Funder Open Access: Please click here for more information on Wiley's compliance with specific Funder Open Access Policies.

7. PUBLICATION PROCESS AFTER ACCEPTANCE

Accepted article received in production

When your accepted article is received by Wiley's production production team, you (corresponding authors) will receive an email asking you to login or register with Author Services. You will be asked to sign a publication licence at this point.

Accepted Articles

The journal offers Wiley's Accepted Articles service for all manuscripts. This service ensures that accepted 'in press' manuscripts are published online very soon after acceptance, prior to copy-editing or typesetting. Accepted Articles are published online a few days after final acceptance, appear in PDF format only, are given a Digital Object Identifier (DOI), which allows them to be cited and tracked, and are indexed by PubMed. After publication of the final version article (the article of record), the DOI remains valid and can continue to be used to cite and access the article.

Accepted Articles will be indexed by PubMed; submitting authors should therefore carefully check the names and affiliations of all authors provided in the cover page of the manuscript so it is correct

for indexing. Subsequently the final copyedited and proofed articles will appear in an issue on Wiley Online Library; the link to the article in PubMed will automatically be updated.

Proofs

Once your paper is typeset you will receive email notification of the URL from where to download a PDF typeset page proof, associated forms and full instructions on how to correct and return the file.

Please note that you are responsible for all statements made in your work, including changes made during the editorial process and thus you must check your proofs carefully. Note that proofs should be returned 48 hours from receipt of first proof.

Early View

The journal offers rapid speed to publication via Wiley's Early View service. Early View (Online Version of Record) articles are published on Wiley Online Library before inclusion in an issue. Note there may be a delay after corrections are received before your article appears online, as Editors also need to review proofs. Once your article is published on Early View no further changes to your article are possible. Your Early View article is fully citable and carries an online publication date and DOI for citations.

8. POST PUBLICATION

Access and sharing

When your article is published online:
• You receive an email alert (if requested).
• You can share your published article through social media.
• As the author, you retain free access (after accepting the Terms & Conditions of use, you can view your article).
• The corresponding author and co-authors can nominate up to ten colleagues to receive a publication alert and free online access to your article.

Now is the time to start promoting your article. Find out how to do that here.

Measuring the impact of your work

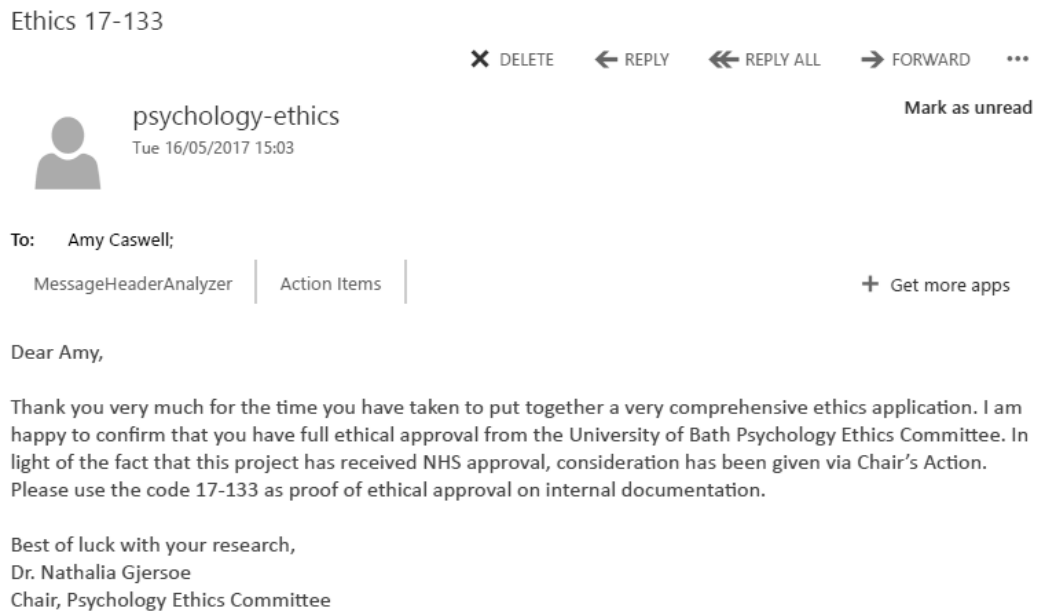
Wiley also helps you measure the impact of your research through our specialist partnerships with Kudos and Altmetric.

9. EDITORIAL OFFICE CONTACT DETAILS

Psycho-Oncology@wiley.com

Author Guidelines Updated 9th May 2017

Appendix Q – University ethics approval notification



Ethics 17-133

DELETE REPLY REPLY ALL FORWARD ...

psychology-ethics
Tue 16/05/2017 15:03

Mark as unread

To: Amy Caswell;

MessageHeaderAnalyzer | Action Items | + Get more apps

Dear Amy,

Thank you very much for the time you have taken to put together a very comprehensive ethics application. I am happy to confirm that you have full ethical approval from the University of Bath Psychology Ethics Committee. In light of the fact that this project has received NHS approval, consideration has been given via Chair's Action. Please use the code 17-133 as proof of ethical approval on internal documentation.

Best of luck with your research,
Dr. Nathalia Gjersoe
Chair, Psychology Ethics Committee

Appendix R – HRA approval notification

NHS
Health Research Authority

Dr Amy Caswell
Taunton and Somerset NHS Foundation Trust
Department of Clinical Psychology
10 West, University of Bath, Claverton Down
Bath
BA2 7AY

Email: hra.approval@nhs.net

08 May 2017

Dear Dr Caswell

Letter of HRA Approval

Study title:	**An experimental investigation of the impact of differential information-provision on the experience of shame in cervical cancer (V1)**
IRAS project ID:	**217863**
Protocol number:	**N/A**
REC reference:	**17/WA/0106**
Sponsor	**University of Bath**

I am pleased to confirm that HRA Approval has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

Participation of NHS Organisations in England

The sponsor should now provide a copy of this letter to all participating NHS organisations in England.

Appendix B provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. **Please read *Appendix B* carefully**, in particular the following sections:

- *Participating NHS organisations in England* – this clarifies the types of participating organisations in the study and whether or not all organisations will be undertaking the same activities
- *Confirmation of capacity and capability* - this confirms whether or not each type of participating NHS organisation in England is expected to give formal confirmation of capacity and capability. Where formal confirmation is not expected, the section also provides details on the time limit given to participating organisations to opt out of the study, or request additional time, before their participation is assumed.
- *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* - this provides detail on the form of agreement to be used in the study to confirm capacity and capability, where applicable.

Further information on funding, HR processes, and compliance with HRA criteria and standards is also provided.

IRAS project ID	217863

It is critical that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details and further information about working with the research management function for each organisation can be accessed from www.hra.nhs.uk/hra-approval.

Appendices

The HRA Approval letter contains the following appendices:

- A – List of documents reviewed during HRA assessment
- B – Summary of HRA assessment

After HRA Approval

The document *"After Ethical Review – guidance for sponsors and investigators"*, issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

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

In addition to the guidance in the above, please note the following:

- HRA Approval applies for the duration of your REC favourable opinion, unless otherwise notified in writing by the HRA.
- Substantial amendments should be submitted directly to the Research Ethics Committee, as detailed in the *After Ethical Review* document. Non-substantial amendments should be submitted for review by the HRA using the form provided on the HRA website, and emailed to hra.amendments@nhs.net.
- The HRA will categorise amendments (substantial and non-substantial) and issue confirmation of continued HRA Approval. Further details can be found on the HRA website.

Scope

HRA Approval provides an approval for research involving patients or staff in NHS organisations in England.

If your study involves NHS organisations in other countries in the UK, please contact the relevant national coordinating functions for support and advice. Further information can be found at http://www.hra.nhs.uk/resources/applying-for-reviews/nhs-hsc-rd-review/.

If there are participating non-NHS organisations, local agreement should be obtained in accordance with the procedures of the local participating non-NHS organisation.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application

IRAS project ID	217863

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/.

HRA Training

We are pleased to welcome researchers and research management staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

Your IRAS project ID is **217863**. Please quote this on all correspondence.

Yours sincerely

Miss Lauren Allen
Assessor

Email: hra.approval@nhs.net

Copy to: *Professor Jonathan Knight (Sponsor contact)*

Appendix S – University sponsor assessment of minor amendments

Professor Jonathan Knight BSc, MSc, PhD
Pro-Vice-Chancellor Research

Vice-Chancellor's Office
Bath BA2 7AY
Tel: 01225 386141
Email: j.c.knight@bath.ac.uk

Amy Caswell
Department of Psychology

18 July 2017

Dear Amy

Re: minor amendments to REC 217863: An experimental investigation of the impact of differential information-provision on the experience of shame in cervical cancer

This is to confirm the sponsor of this study, the University of Bath, is satisfied that the changes to the recruitment numbers is a minor amendment approval of which you will be seeking from the appropriate NRES Committee.

Yours sincerely

Professor Jonathan Knight
Pro-Vice-Chancellor Research

Appendix T – Participant Information Sheet

Participant Information Sheet (V2.1)
Research study: Psychological experiences of women with cervical cancer
5th May 2017

We would like to invite you to take part in our research into the psychological experiences of women with cervical cancer.
The study is anonymous and is completed online whenever is convenient for you. It will last about 20-30 minutes. You can participate in the study if you are a women, over the age of 25, with a current or past diagnosis of cervical cancer. As a small way of saying thank you for completing the study, we will make a donation to a charity supporting women's health on your behalf.
Joining the study is entirely up to you. Before you decide if you want to participate, we would like you to understand why the research is being done and what it would involve for you.
Please read the following information carefully.

About the study
Greater attention is now being paid to the psychological experiences of women with cervical cancer. The charity The Eve Appeal highlighted that there is still a lot we don't know about how cervical cancer affects women psychologically, meaning we don't always know how best to support women.
Women with cervical cancer can experience a lot of different emotions. We are interested in what might lead to difficult emotions and what could reduce difficult emotions. We hope the research will help us to improve the experience of women with cervical cancer.

What would taking part involve?
In the study, we will ask you some questions about yourself, your diagnosis and your psychological wellbeing. We will then show you some information about cervical cancer, before asking you to complete further questions.
The study will last 20-30 minutes. It is anonymous, and your name won't be linked to your answers. The study is completed online, so you won't need to meet a researcher or attend any sessions. You can do it at a time convenient for you.
The study is separate from your standard care from your medical team. Choosing to participate will not affect your care in any way, and participation is entirely voluntary.

Who is involved in the study?
The study is being run through the University of Bath. The researchers involved in the project are:

- Dr Amy Caswell - Clinical Psychologist in Training, University of Bath – Main researcher
- Dr Cara Davis - Clinical Psychologist and Clinical Tutor at Bath University – Project Supervisor
- Dr Megan Wilkinson-Tough - Clinical Psychologist and Clinical Tutor at Bath University – Project Supervisor
- Dr Sam Cole - Clinical Psychologist, University Hospitals Bristol NHS Foundation Trust – Project Supervisor

The study has been approved by the NHS, Wales REC 3 and the University of Bath, who have given ethical approval for it.

Why is this research important?
We want to ensure that women with cervical cancer receive the best possible psychological care and support through their illness, and ensure that any distress is reduced. We don't feel

that enough is being done to understand the experiences of women with cervical cancer, and want to start making changes to this.
We hope that this research will inform psychological support for women with cervical cancer. By completing the study you are helping us get one step closer to this goal.

What are the possible benefits of taking part?
We cannot promise you any direct benefits from participating but taking part will help the support provided to those with cervical cancer.
By choosing to take part in the study you are helping us understand the experiences of women with cervical cancer - the more we know, the more we can do to support women in similar situations to yourself.
To say thank you for participating we will also make a £1 charity donation on your behalf. The donation will go to charities supporting women with cervical cancer.

What are the possible disadvantages and risks of taking part?
Your wellbeing is very important to us, and we have been careful to make sure there are no disadvantages to you.
However, as part of the study we will ask you questions that you might find sensitive, including questions about your diagnosis and your mental health. We will also give you information about cervical cancer. We do recognise that answering questions about your illness could bring up some distressing emotions for some women.
If you find yourself feeling upset or distressed you can stop the study at any time without penalty. If you want to stop please press the button saying "exit the study".
If you experience any severe distress and feel you need support, please contact your lead clinical nurse or GP. Further sources of support include:

- Jo's Cervical Cancer Trust (www.jostrust.org.uk).
- The Samaritans (phone 116 123)

You can also contact the lead investigator for the study, Dr Amy Caswell, at a.caswell@bath.ac.uk or by phoning [redacted]. If you have a query about the study and do not want to contact the lead investigator directly, please Dr Cara Davis, c.davis@bath.ac.uk, or Dr Megan Wilkinson-Tough, m.wilkinson-tough@bath.ac.uk.

Further information:
How do we keep your information confidential? Your answers to the questionnaire will be completely anonymous. You will not be asked to give your name or email address. This means your name will not be linked to any answers you give, and will not be included in any write ups of the study.
What happens if I change my mind about participating? You can change your mind about participating in the survey at any point before submitting your answers, with no negative consequences. If you want to leave the study please press the button saying "exit the study". At the end of the study you will confirm that you are happy for your answers to be submitted to the researchers. After you have submitted your answers we cannot withdraw this information because it will have been submitted anonymously and we will not be able to identify that it was yours.
What will you do with the results of the study? The results from the study will be written up and submitted as part of a postgraduate academic study programme, and might be submitted for publication in a journal. The results might also be sent to charities and other services supporting women with cervical cancer, so that they can show to results on their website or in their services. The results will be aggregated and your name or any identifying information will not be written in any write-up.
If you would like to know the aggregate results of the study then please email the main researcher, a.caswell@bath.ac.uk, and you will be sent them when available. The contact details you provide will not be linked with your research responses in any way and will be stored securely. Please note we will not be able to send you your individual results, only the aggregated results.

The anonymous data will be kept on file in accordance with UK data laws. The anonymised data will be stored, and might be distributed to other research institutes for research purposes should they request it. Your name will not be distributed at any point.

Appendix U – Consent process (completed in Qualtrics)

UNIVERSITY OF BATH

CONSENT FORM

Research study: Psychological experiences of women with cervical cancer

Please answer the following questions to the best of your knowledge

	YES	NO
DO YOU CONFIRM THAT YOU:		
• Are over the age of 25	☐	☐
• Have a past or current diagnosis of cervical cancer	☐	☐
• Are fluent in English	☐	☐
HAVE YOU:		
• been given and read the information sheet dated 5th May 2017 (V2.1)	☐	☐
• received enough information about the study for you to make a decision about your participation?	☐	☐
DO YOU UNDERSTAND:		
• that you are free to withdraw from the study and free to withdraw your data prior to final consent at any time	☐	☐
• without having to give a reason for withdrawing?	☐	☐
• That your responses will be kept anonymously	☐	☐

I hereby fully and freely consent to my participation in this study

I understand the nature and purpose of the procedures involved in this study. These have been communicated to me on the information sheet accompanying this form.
I understand and acknowledge that the investigation is designed to promote scientific knowledge and that the University of Bath will use the data I provide for no purpose other than research.
I understand the data I provide will be **anonymous**. No link will be made between my name or other identifying information and my study data.
I understand that the University of Bath may use the data collected for this study in a future research project but that the conditions on this form under which I have provided the data will still apply.

Participant's signature: _____ Date: _____

Name in BLOCK Letters: _____

Landing page if person indicates that they do not meet eligibility criteria

Thank you for taking the time to read the information about our study.

Unfortunately, from the information you provided, you are not eligible to participate in the study at this time.

We would like to thank you very much for the time you took to read the information sheet and for offering to participate, we appreciate it.

Landing page if the person indicates that they need more information

Thank you for taking the time to read the information about our study.

You have indicated that you either wanted more information about the study before you decide to participate, or that there was some information that you didn't understand.

You can either contact the researcher, Dr Amy Caswell, for more information (a.caswell@bath.ac.uk) OR

- Please click here to re-read information about the study
- Please click here if you do not want to continue, and wish to exit the study

Landing screen if person indicates that they do not want to complete the study

Thank you for taking the time to read the information about our study.

You have indicated that you do not wish to participate in the study.

Thank you very much for your time, we appreciate it.

Final consent

Having participated in this study

I agree to the University of Bath keeping and processing the data I have provided during the course of this study. I understand that these data will be used only for the purpose(s) set out in the information sheet, and my consent is conditional upon the University complying with its duties and obligations under the Data Protection Act.

Participant's signature: _____ Date: _____

Name in BLOCK Letters: _____

Appendix V – Brief procedure

Below is a list of the measures that will be completed in the study. All measures are include below.
As the study will be completed online using the survey software Qualtrics, all measures will be uploaded to Qualtrics and formatted according to its software. Please see IRAS checklist documents for questionnaires as uploaded to Qualtrics.

The following measures will be completed in the following order:

1. Baseline questionnaires:
    a. Demographic questionnaire
    b. Measure of lifetime depression and anxiety
    c. Hospital anxiety and depression scale (HADS; validated questionnaire)
    d. Warwick-Edinburgh Mental Wellbeing Scale (WEMWS; validated questionnaire)
    e. State Shame and Guilt Scale (SSGS; validated questionnaire) & Adapted State Shame and Guilt Scale (aSSGS) combined.
2. Multiple choice quiz
3. Information provision procedure*
4. Post information questionnaires*
    a. SSGS (validated questionnaire) & aSSGS
    b. Brief mood ratings
    c. Measures of intended behaviour
5. Brief version of multiple choice quiz (knowledge check)

**There are three levels of information. Participants will complete the post information questionnaires after each level of information.*

Appendix W – Baseline questionnaires

Note – copyrighted questionnaires have not been included.

Demographic information

General Demographic information:

1. How old are you? (space to respond)

2. What is your highest level of education?
    a. Less than GCSE
    b. GCSE (or equivalent)
    c. A-levels (or equivalent)
    d. Undergraduate degree
    e. Postgraduate degree
    f. Prefer not to answer

3. Where do you currently live?
    a. UK
    b. USA
    c. Other (please provide details)
    d. Prefer not to answer

4. What is your ethnic group? Choose one option that best describes your ethnic group or background
    a. White
    b. Mixed/multiple ethnic groups
    c. Asian/Asian British
    d. Black/ African/ Caribbean/ Black British
    e. Other ethnic group
    f. Prefer not to answer

5. How would you describe your current relationship status? Please choose one option that best describes your current relationship status.
    a. Single
    b. In (a) non-exclusive or casual relationship(s)
    c. In a committed/exclusive relationship
    d. Married or domestic partnership
    e. Widowed
    f. Divorced or separated
    g. Other (please provide details)
    h. Prefer not to answer

6. How did you find out about this study
    a. Online
    b. Word of mouth
    c. Bristol NHS Trust
    d. London NHS Trust
    e. Other NHS trust

f. Prefer not to answer
g. Other (please provide details)

Cancer demographic information:

The following questions ask details about your cancer diagnosis. Lots of women don't know this level of detail – this is absolutely normal, and you should simply choose "I don't know", or the answer that best fits.

7. What type of cervical cancer have you been/were you diagnosed with?
    a. Squamous cell cancer
    b. Adenocarcinoma
    c. Other (please provide details)
    d. I don't know

8. What stage is your cancer?
    a. 1
    b. 2
    c. 3
    d. 4
    e. I'm in remission
    f. I don't know

9. What treatment have you had for cervical cancer? Please tick as many as are relevant – if you know the specific type of therapy please tick the appropriate box, otherwise tick the general type of treatment
    a. Surgery (I don't know specific details)
        i. Conization/cone biopsy
        ii. Hysterectomy
        iii. Radical trachelectomy
        iv. Bilateral salpingo-oophorectomy
        v. Pelvic exenteration
    b. Radiation therapy
        i. External radiation therapy
        ii. Internal radiation therapy
    c. Chemotherapy
    d. Targeted (biological) therapies

10. When were you diagnosed with cervical cancer?
    a. Less than 1 month ago
    b. Between 1 and 6 months ago
    c. Between 6 months and a year ago
    d. Between a year and 2 years ago
    e. Between 2 and 5 years ago
    f. More than 5 years ago

Knowledge of cervical cancer, general information

11. How would you rate your knowledge of cervical cancer?

1 (I have no knowledge) – 10 (I am very knowledgeable)

Lifetime depression and anxiety:

12. Have you ever had a period of time during your life when you were feeling depressed or down most of the day nearly every day?
    a. Yes, once
    b. Yes, more than once
    c. No

13. Have you ever had a period of time during your life when you were feeling very anxious or worried most of the day nearly every day?
    a. Yes, once
    b. Yes, more than once
    c. No

Support from mental health services:

14. Since being diagnosed with cervical cancer have you received support for mental health needs from your GP, mental health services or voluntary organisations?
    a. Yes (please provide any details you can remember)
    b. No

Adapted State Shame and Guilt Scale

Adapted from the state shame and guilt scale.

The following are some statements that may or may not describe how you are feeling RIGHT NOW. Please rate each statement using the 5 point scale below. Remember to rate each statement based on how you are feeling RIGHT AT THIS MOMENT.

I think other people feel good about me	1----------2----------3----------4----------5
I think other people want me to sink into the floor and disappear	1----------2----------3----------4----------5
I think other people feel remorse, regret about something I have done	1----------2----------3----------4----------5
I think other people see me as worthwhile, valuable	1----------2----------3----------4----------5
I think other people see me as small	1----------2----------3----------4----------5
I think other people feel tension about something I have done	1----------2----------3----------4----------5
I think other people see me as capable, useful	1----------2----------3----------4----------5
I think other people see me as a bad person	1----------2----------3----------4----------5
I think other people cannot stop thinking about something bad I have done	1----------2----------3----------4----------5
I think other people feel proud of me	1----------2----------3----------4----------5
I think other people see me as humiliated, disgraced	1----------2----------3----------4----------5

I think other people think I should apologise, confess	1----------2----------3----------4----------5
I think other people feel pleased about something I have done	1----------2----------3----------4----------5
I think other people see me as worthless, powerless	
I think other people feel bad about something I have done	1----------2----------3----------4----------5

Multiple Choice Quiz

Please answer the following questions about cervical cancer. Please select one answer per question.

1. Where is the cervix located in the body?
    a. In the ovaries
    b. The lower, narrower part of the uterus
    c. In the stomach
    d. In the feet
2. Cervical cancer is cancer of the…
    a. Breast
    b. Cervix or neck of the womb
    c. Brain
    d. Blood
3. How many women with cervical cancer are under the age of 50?
    a. Less than 10%
    b. Less than 50%
    c. More than 50%
    d. More than 90%
4. Cervical cancer is mainly associated with… *
    a. Infection with human papillomavirus (HPV)
    b. Smoking
    c. Infection with hepatitis
    d. Drinking alcohol
5. 5. What are the symptoms of cervical cancer in the early stages?
    a. Typically, there are no obvious symptoms
    b. Abdominal cramps
    c. Nausea
    d. Anaemia
6. Human papillomavirus (HPV) is spread by… *
    a. Coughing and sneezing
    b. Not washing your clothes properly
    c. Intimate contact with infected people, especially through sex
    d. Contact with contaminated surfaces
7. HPV can cause…
    a. A cough
    b. Changes in cervical cells
    c. Changes in iron levels in the blood
    d. Changes in hormones
8. Approximately how many people will get HPV at some point in their lifetime? *

*these questions will be used to establish the baseline knowledge of participants

Appendix X – Information Provision Procedure

Note - Three levels of information about HPV will be presented to participants. Participants will see one level of information at a time. They will click through to the next page once they have read the information. The three levels of information are:

Information level 1: Both conditions will first receive general information about HPV.

Information level 2: Condition A will receive information on the high prevalence of HPV. Condition B will receive information that HPV is sexually transmitted.

Information level 3: Condition A will receive information that will receive information that HPV is sexually transmitted. Condition B will receive information on the high prevalence of HPV.

First participants will see an instruction page with the following text:

For the next part of the study you will be shown some information about cervical cancer. You will then be asked questions about how you feel about that information. You will see three pieces of information, and will answer questions after each.
Please read each piece of information carefully before answering the questions about it.

On the second page they will see the relevant information about HPV, depending on the level of information. Information will be preceded by the statement:

Please take a minute to read the following information:

General information:

"A virus called human papillomavirus (HPV) is now known to be involved in the development of cervical cancer (cancer of the cervix or neck of the womb).
For most women, the immune system clears the virus and there are no health problems associated with it.
However, if infection persists, it can lead to abnormalities in the cells of the cervix.
These cells then have an increased risk of becoming cancerous."

Information that HPV is sexually transmitted:

"HPV is transmitted through intimate skin-to-skin contact during sex. It is described as being sexually-transmitted."

Information on the high prevalence of HPV:

"Many people are surprised to discover just how common HPV is. Currently, around 80% of people will be infected with HPV at some point in their lives. That means that of every 5 people you know, approximately 4 will have had the virus."

Appendix Y – Post-information questionnaires

Note – all post-information questionnaires will be prefaced with the statement "take a minute to think about the information that you just read [about HPV and cervical cancer/that HPV is sexually transmitted/that HPV is very common, with around 80% of people being infected with it during their lifetime (deleted as appropriate)]"

State Shame and Guilt Scale
Same as in baseline measures.

Adapted State Shame and Guilt Scale
Same as in baseline measures.

Brief mood ratings
When you think about the information you just read [about HPV/about HPV being very common/about HPV being sexually transmitted)…

1. How would you rate your mood? 0=very low in mood, 10= very high in mood
2. How would you rate your wellbeing? 0=very poor wellbeing, 10 = very good wellbeing
3. How would you rate your anxiety? 0=not at all anxious, 10 = very anxious

Appendix Z – Debrief materials

Thank you for taking the time to participate in our study, we appreciate it. To thank you for participating, we will donate £1 to a charity supporting women with cervical cancer. Thanks to your participation our donation is growing!

Background to the study

The study was an investigation into the experiences of women with cervical cancer, particularly concerning knowledge and information about HPV. As you were told, cervical cancer is caused by Human Papilloma Virus (HPV). HPV is described as a sexually transmitted virus, as it is transmitted through skin-to-skin contact during sex. The virus is very common, and it is thought that around 80% of people will contract it at some point in their lifetime. Most people won't develop any problems from HPV, although it can cause changes in cervical cells, which then have an increased risk of becoming cancerous.

Research has found that cervical cancer patients can experience raised levels of depression and anxiety. They can also experience a lot of shame about their diagnosis. We wonder whether shame, anxiety and depression might be because of knowledge that HPV is sexually transmitted. This has never been researched in women with cervical cancer. On the other hand, knowing how common HPV is can reduce any feelings of shame, and we wonder whether this could be helpful information for cancer patients.

The study

In the study, you first answered a number of questions about yourself. You then read general information about HPV, before answering the questions about how you felt. You then either read information that HPV is sexually transmitted *OR* that it is very common, before answering how you felt. You then read the other information (HPV is sexually transmitted *OR* is very common) before saying how you felt.

Half the participants read the information that HPV is sexually transmitted first, and half read that it is very common first.

This will allow us to look at how information that HPV is sexually transmitted is experienced by women, and whether the information that HPV is very common reduces any negative feelings.

We hope that this research will inform us of how to present this information to women, to reduce any distress arising from it.

If you need further support

Once again, we thank you for taking the time to do this study. We really appreciate the contribution you have made to understanding the experiences of women with cervical cancer.

We hope that participating in this study has been interesting. If you have any questions or concerns, please contact Dr Amy Caswell at a.caswell@bath.ac.uk, or either supervisor (c.davis@bath.ac.uk; m.wilkinson-tough@bath.ac.uk).

If the study has made you feel you might benefit from further emotional support, please contact your lead clinical nurse or GP. Jo's cervical cancer trust is also an excellent source of support for women with cervical cancer (www.jostrust.org.uk).

If you feel you need more immediate support or are concerned for your immediate wellbeing, please contact the Samaritans by calling them on 116 123 – phone calls are free from UK landlines and mobiles.

Finally, we would like to say thank you once again for participating in the study – we really appreciate your time and contribution.

Blank page