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A Feasibility Study of Acceptance and Commitment Therapy to Promote the Wellbeing of Carers of People with Dementia

&

Clinical Research Portfolio

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Systematic Review

Major Research Project

Chapter One: A Systematic Review of Psychological Interventions for Carers of People with Dementia

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ABSTRACT

Background: Dementia carers may experience reduced wellbeing associated with this role. Further scrutiny regarding how best to provide psychological support for this group is indicated. Previous reviews have highlighted potential benefits from psychoeducation, cognitive behavioural, and multicomponent approaches for reducing distress (Gallagher-Thompson & Coon, 2007; Elvish et al., 2013). However, the use of non-standard methods of quality assessment have limited the strength of interpretations and implementation guidance for professionals.

Objective: This review aimed to update and improve a previous review of psychological interventions for carers of people with dementia; narrowing the search focus, describing research developments, and using a standardised method of assessing potential sources of bias associated with randomised controlled trials.

Method: Randomised controlled trials of psychological interventions for dementia family caregivers published between 2012 and 2016 were systematically searched across five research databases. Data were extracted, synthesised and summarised; describing the characteristics of research participants, interventions, comparisons, and outcomes. The Cochrane Risk of Bias tool was used to assess the likely bias introduced by research methodologies.

Results: Fourteen RCT studies were identified and demonstrated a clear expansion of the evidence base: reporting on a range of psychological interventions using diverse delivery methods and outcome measures. Risk of bias was variable across studies and highlighted areas of strengths (randomisation and data handling) and potential for improvements (clearer reporting of research methods).

Conclusions: Results reflected an expansion of the breadth of research regarding psychological support for dementia carers and evidence development of the efficacy of cognitive behavioural approaches. This area of research would further benefit from improvements in designing and reporting bias-reducing methods.

INTRODUCTION

Dementia has been estimated to directly affect 46.8 million people around the world as of 2015 and this figure is predicted to triple by 2050 (World Alzheimer Report, 2016). Informal carers of people with dementia in the UK make up an estimated 670,000 people (Alzheimer's Society, 2014). The wellbeing of carers of people with dementia (CPwD), their mental health needs, and the effectiveness of psychological interventions that support them is not fully understood. The World Health Organisation report, Dementia: A Public Health Priority, highlights the wide-ranging detrimental effects that CPwD experience in terms of physical, psychological, social and economic impact (WHO, 2012). The greatest impact of dementia is purported to be upon the quality of life of both individuals and their carers (World Alzheimer Report, 2016). Several hypotheses can be drawn about the lived experience of caring for someone with dementia and the literature exploring this is expanding. However, there is limited evidence to guide mental health professionals' decisions about how best to support this group of people.

Understanding of the experience of caring for a family member with dementia is developing within the empirical literature. Reductions in psychological wellbeing, such as depression, burden, and stress have been reported by CPwD (Burns & Rabbins, 2000). The levels of distress associated with caring for a relative with dementia is thought to be under-reported by carers and can also be underestimated by professionals (Neil & Bowie, 2008). More recently, research into the health of CPwD has begun to focus more broadly on wellbeing as well as, or instead of, associated pathologies or symptoms of being a carer (Márquez-González, Romero-Moreno, & Losada, 2010; Losada et al., 2015; Losada, Márquez-González, & Romero-Moreno, 2011).

However, CPwD are a heterogeneous population in terms of characteristics (age, relation, gender, education, occupation, etc.), background (socioeconomic status, experience of caring, previous relationship quality with recipient of care, etc.), burden of care they experience (level of caring responsibility required), and psychological wellbeing (Zarit & Femia, 2008). Therefore, people's experiences of providing care to their family members with dementia differ greatly. The experience of caring for a person with dementia has the potential to contribute to both improved psychological wellbeing (Chappell & Reid, 2002; Sabat, 2011; Lloyd, Patterson & Muers, 2016), and reduced psychological wellbeing (Burns & Rabbins, 2000; Hirst, 2005; Neil & Bowie, 2008). Zarit and Femia (2008) highlighted a conceptual trap that researchers may fall into whereby pathology is assumed in all carers or that the role of caregiver inevitably results in negative experiences; they suggest therefore that support is offered to carers in a sensitive and responsive manner.

In a recent review, quantitative and qualitative evidence regarding psychological interventions for CPwD was evaluated for studies published between 2005 and 2011 (Elvish *et al.*, 2013). Twenty studies met eligibility criteria and were included; 17 of these used randomised controlled trial (RCT) methodology and three utilised qualitative methods. This review incorporated and adapted two previous reviews considering psychological interventions and for CPwD (Pinquart & Sörensen, 2006) and for distress in family caregivers of older adults in general (Gallagher-Thompson & Coon, 2007). The search terms related to intervention approach were limited in their reach; researchers chose to specify CBT, family or systemic therapies only. The authors chose to include 'Mild Cognitive Impairment' as a search term, which poses a potential dilution of results and the conclusions that can be drawn with regard to dementia specifically.

The main findings of the Elvish et al. (2013) review were: i) four different types of interventions researched within the literature (psychoeducation, psychotherapy-counselling, multi-component, technology-based), ii) evidence supported use of psychological interventions, especially cognitive behavioural approaches, to improve wellbeing, reduce symptoms of anxiety and depression, and change attitudes towards caregiving iii) multicomponent and technology-based interventions using combined individual and group sessions were most effective. There were few studies in each group and it is not possible therefore to make clear comparisons between the relative efficacy of psychological intervention modalities.

The authors developed and used their own quality criteria, informed by standardised measures of research quality (CONSORT, 2010, STROBE 2007, CASP, 2006). Quality tools used were designed post data extraction and are therefore subject to potential bias in the interpretation of results. The total scores presented within the review subsequently provide restricted information for the reader. The reviews conducted to date have not systematically and specifically evaluated the methodological quality of RCT studies, for example potential sources of bias that may lead to misrepresentative findings.

Aims and Objectives

There has been five years of research concerning psychological interventions for CPwD since the review by Elvish and colleagues (2013) was conducted and likely further developments within this evidence base have been reported. There is a need to address some issues with previous reviews and update these to include new studies published since 2011. It is also necessary to clearly characterise the literature in terms of populations treated, the range of interventions tested, comparison conditions used, and the types of outcomes that have been explored and reported. To make decisions about the best approach to supporting CPwD, the review sought to evaluate the quality of the literature, especially in terms of the risk of bias in intervention studies.

METHODOLOGY

A search of MEDLINE, EMBASE, PsychINFO, CINAHL, and ASSIA databases was conducted using predefined search terms for RCT studies published between 2012 to 2016; exclusively including articles published after those reviewed by Elvish and colleagues (2013). Following this, record titles and abstracts were screened against the eligibility criteria. This eligibility screening process was repeated by assessing the full article of the remaining selection of records. Data extraction (i.e. of study population, intervention, control group, and outcome measure type) was completed for the final eligible articles. Evaluation using the Cochrane Risk of Bias Tool (Lundh & Gøtzsche, 2008; Higgins et al., 2011) was also conducted on all final records by two assessors independently.

Eligibility Criteria

The inclusion/exclusion criteria were based on those used for quantitative studies in the previous review (Elvish *et al.*, 2013):

- The person who was the focus of the caregivers' attention had a diagnosis of dementia (Alzheimer's, Fronto-temporal, Vascular).
- The primary/significant focus of the outcome measures was a psychosocial measure of carer wellbeing.
- The intervention was underpinned by a psychological theory of change.
- Paper in English language
- The study used a randomised controlled trial methodology.

The wording of the first point was adapted from “the care receiver had a dementia” to make the search more specific to care recipients with a formal dementia diagnosis. The third criterion was defined as a recognised evidence-based psychological therapy (EBT) or where there was clear evidence that an intervention was based on an EBT model or theory. The last point was an additional criterion not previously stipulated in previously conducted reviews.

Search Terms

The search terms listed in Table 1 were used as the basis for literature searches. See appendix 1.2 for full search strategy employed for each database.

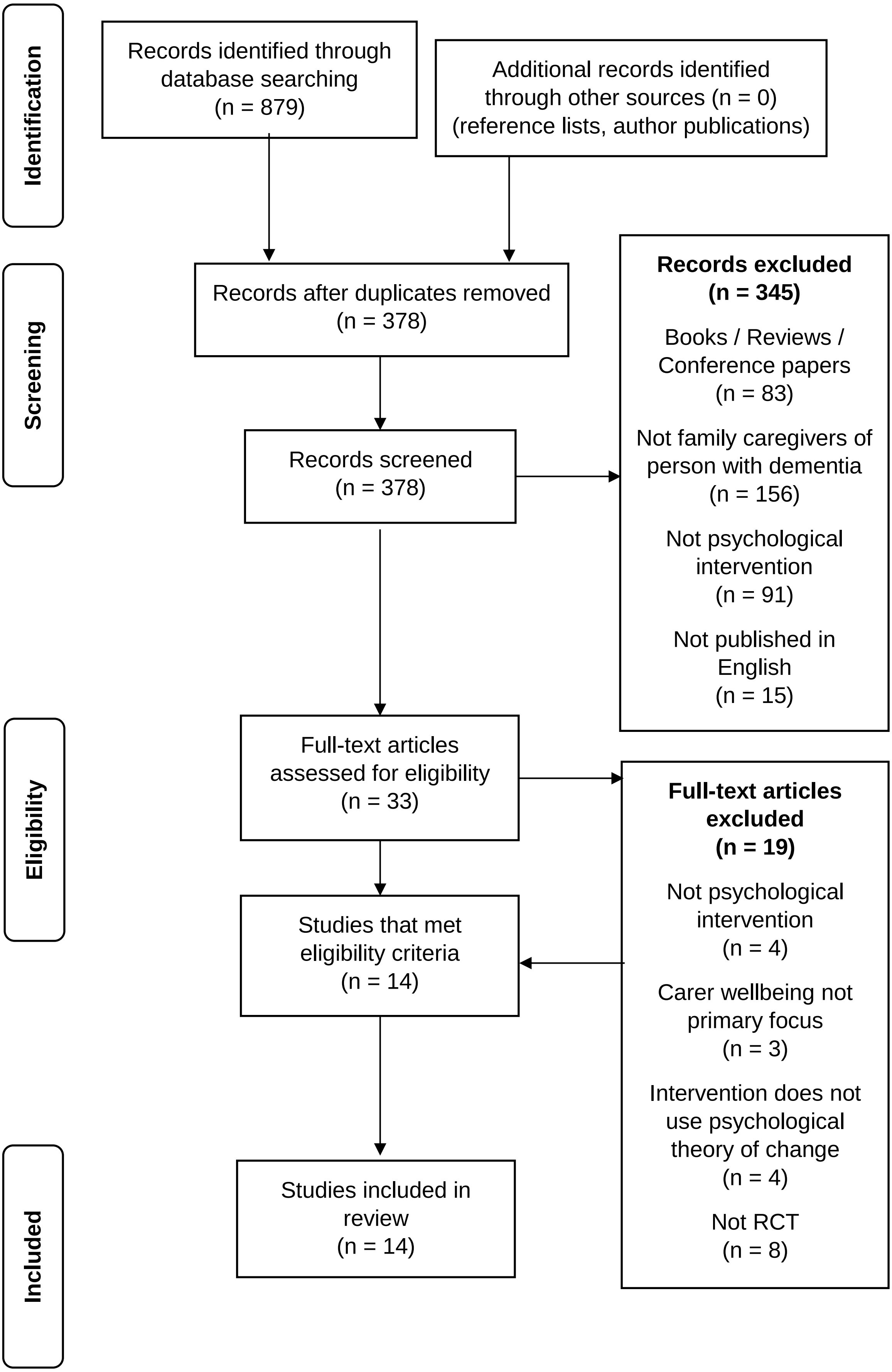
Table 1. Search terms for systematic literature review of psychological interventions for carers of people with dementia.

Population 1	Population 2	Intervention
Caregiver	Dementia	Psychotherapy
Caregiving	Alzheimer's	Cognitive Behavioural Therapy
Care		CBT
Caring		Family
		Systemic
		Psychological
		Psychosocial
		ACT
		Mindfulness
		Training

Search Outcome

Figure 1 provides an overview of the search, screen and eligibility assessment process followed within this review. A total of 378 studies were identified from database searches excluding duplicates. This was reduced to 33 following screening by manually assessing title and abstract. Full articles were subsequently assessed for eligibility and 18 further studies were excluded. A final total of 14 articles were included for data extraction and evaluation.

Figure 1. Flow Diagram of Selection of Papers for Inclusion in the Systematic Review



Quality Appraisal

The Cochrane Risk of Bias Tool (Lundh & Gøtzsche, 2008; Higgins et al., 2011) was used to assess all eligible articles. Two assessors evaluated each article, assigning ‘low’, ‘high’ or ‘unclear’ risk of bias across all seven domains: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting, and other bias. Evidence of each was recorded and where disagreement occurred consensus was reached via discussion. Where a decision could not be reached a third person (research supervisor) provided a final opinion.

RESULTS

A total of 14 eligible peer-reviewed journal articles were included in this review. Table 2 provides relevant details of study design and findings. The selection included international research from 11 countries across four continents: Europe (6), North America (5), Asia (2), and South America (1).

Populations Examined

Research articles had a median sample size of 102 CPwD (IQR: 72.5-189.5). Mean age of carers ranged from 54.8 to 72.0 years. All studies reported a higher proportion of female carers than male participants; mean of 76% female family caregivers (range: 65-96%). Caregivers tended to be spouses or adult children, however there was variation in the relative proportions of each type of relationship. Some of the reporting of the proportion of participants of each relationship type to care recipients was not always clear or was absent.

Alzheimer’s Dementia was the most common diagnosis of care recipients with five studies using this as an inclusion criterion (Au, 2015; Cristancho-Lacroix *et al.*, 2015; Kamkhagi *et al.*, 2015; Gonyea, López & Velásquez, 2016; Wilz & Soellner, 2016), six studies reporting 65-77% of care recipients having this diagnosis (Waldorff *et al.*, 2012; Kajiyama *et al.*, 2013; Chen *et al.*, 2015; Losada *et al.*, 2015; Prick *et al.*, 2015; Tremont *et al.*, 2015), and the remaining three studies not reporting on this detail (Livingston et al., 2013; Moore et al., 2015; Whitebird et al., 2012).

The wellbeing status of caregivers varied across the studies: six studies excluded participants with mental health diagnoses (Kajiyama *et al.*, 2013; Moore *et al.*, 2013; Chen *et al.*, 2015; Kamkhagi *et al.*, 2015; Tremont *et al.*, 2015; Wilz & Soellner, 2016); five stipulated that caregivers display specific symptoms (e.g. depressive

Table 2. Characteristics and Findings of Studies

Behavioural Activation							
Author	**Country**	**Sample**	**Study Arms**	**Manual-Protocol**	**Treatment Length**	**Main Finding**	**Outcome Measures***
Au, 2015	China	96 randomised 76 females, 17 males Intervention n = 51 (mean age = 56.90) Control n = 45 (mean age = 55.50)	1 – Behavioural Activation and Psychoeducation (PsyEd with BA) 2 – Psychoeducation only Control (PsyEd)	BA –pleasant event scheduling and effective communications. PsyEd - adapted Chinese version of "Coping with Caregiving" (Gallagher-Thompson)	Both conditions: 8 fortnightly telephone sessions (15-20 minutes) over 4 months	BA: Significant decrease of depressive symptoms.	CES-D
Moore et al., 2013	USA	100 randomised 74 females, 26 males Intervention n = 49 (mean age = 70.86) Control n = 51 (IS mean age = 71.33)	1 – Pleasant Events Programme (PEP) Intervention 2 – Information Support (IS) Control	PEP – adapted manualised brief BA therapy (Lejuex et al. 2001). IS – guided self-help. Supportive psychotherapy if requested.	Both conditions: 4 weekly home therapy sessions (1hr) over 6 weeks, 2 weekly phone sessions (15min-1hr)	PEP > IS: Significant reduction of depressive symptoms, and negative affect (Not over 1 year). PEP > IS: CVD risk significantly lowered post-treatment.	CES-D PANAS SSS D-dimer and Interleukin-6

Cognitive Behavioural Therapy							
Author	**Country**	**Sample**	**Study Arms**	**Manual-Protocol**	**Treatment Length**	**Main Finding**	**Outcome Measures***
Gonyea, López, & Velásquez, 2016	USA	67 randomised 64 Females, 3 Males Intervention n = 33 (mean age = 55.91) Control = 34 (mean age = 55.50)	1 – CBT 2 – Psychoeducation (PED) Control	CBT – ABC problem-solving approach (sensitive to Latino culture). PED – psychoeducation, peer support for stress, home safety tasks.	Both conditions: 5 weekly group sessions (1.5hr) 4 three-weekly booster telephone sessions (10-15mins) over 12 weeks	CBT > PED reduced caregiver distress, increased caregiver self-efficacy and reduced depressive symptoms.	Spanish versions: NPI-S NPI-D CES-D RSCSE STAI
Wilz & Soellner, 2016	Germany	229 randomised 157 Females, 34 Males Mean Age = 62.1 Intervention 1 n = 50 Intervention 2 n = 76 Control (PMR) n = 53 Control (UC) n = 50	1 – Telephone CBT 2 – Telephone CBT (Non-randomised) 3 – Progressive Muscle Relaxation (PMR) Control 4 – Untreated Control (UC)	CBT interventions – TeleTAnDem (Wilz et al. 2011) PMR – education and experiential session, plus telephone support to use written material and CD training program	All interventions: 7 telephone sessions:1-4 weekly, 5-6 fortnightly, 7 one month later (1hr) over 3 months (face-to-face first session for Groups 1&3)	CBT>PMR/UC: improved emotional wellbeing, global body complaints, and exhaustion CBT: applicable for family dementia caregivers by telephone	German CES-D Caregiver body complaints (GBB-24) Emotional Well-being VAS

Cognitive Behavioural ‘Third Wave’ Therapy							
Author	**Country**	**Sample**	**Study Arms**	**Manual-Protocol**	**Treatment Length**	**Main Finding**	**Outcome Measures***
Losada et al., 2015	Spain	135 randomised 114 females, 21 males CBT Intervention n = 42 (mean age = 61.48) ACT Intervention n = 45 (mean age = 61.69) Control n = 48 (mean age = 62.28)	1 – CBT 2 – ACT 3 – Minimal Support Control Group (MS)	CBT – based on REACH study (Gallagher-Thompson et al. 2003) ACT – specifically designed for caregivers (Adapted Hayes et al. 1999, McCurry 2006) Control – workshop and booklet containing dementia psychoeducation provided.	Interventions: 8 weekly individual sessions (1.5hr) Control: 1 session (2 hr)	CBT and ACT > MS depression reduction (post-intervention – maintained at follow-up for CBT only) ACT > CBT anxiety reduction (post-intervention, no effects at follow-up). ACT and CBT: Significant changes in leisure and dysfunctional thoughts ACT: Changes in experiential avoidance.	Disruptive Behaviors Subscale RMBPC CES-D Tension-Anxiety subscale from POMS LTS EACQ DTCQ

Cognitive Behavioural 'Third Wave' Therapy Continued

Author	Country	Sample	Study Arms	Manual-Protocol	Treatment Length	Main Finding	Outcome Measures*
Whitebird et al., 2012	USA	78 randomised, 69 females, 9 males Mean age = 56.8 Intervention n = 40 (mean age = 56.4) Control n = 38 (mean age = 57.2)	1 – Mindfulness-based Stress Reduction (MBSR) Group 2 – Community Caregiver Education and Support (CCES) Group	MBSR – standardised programme designed to reduce stress and manage difficult emotions through training in mindfulness (Kabat-Zinn, 1990) CCES – active comparison group providing education (dementia, legal and financial issues, community resources, self-care, grief, and loss,), social and emotional support.	Both conditions: 8 weekly group sessions (2.5 hr: 7-8 participants per group), retreat or wellness day (5hr), weekly telephone calls (monthly during 6 month follow-up period).	MBSR > CCES improved mental health, stress and depression (2 months post-intervention). MBSR: feasible, acceptable intervention.	PSS CES-D STAI SF-12 MBCBS MOSSSS

Multi-Component Approach

Author	Country	Sample	Study Arms	Manual-Protocol	Treatment Length	Main Finding	Outcome Measures*
Prick, de Lange, Twisk, & Pot, 2015	Netherlands	111 dyads randomised 80 females, 31 males Mean age = 72 Intervention n = 57 (mean age = 73), Control n = 54 (mean age =71)	1 – Physical exercise and support intervention 2 – Minimal intervention comparison group	Intervention - translated and adapted intervention (Teri et al., 2003) Comparison – usual care plus information bulletins (e.g. car driving and health in dementia)	Intervention: 8 home sessions with dyads (1 hr); first month weekly, next 8 weeks fortnightly (3 months total) Control: 2 monthly bulletins and supportive telephone calls (10 mins)	No benefits over time on any outcomes.	Dutch CES-D Dutch SPICC Dutch RMBPC General health on single-item scale. Salivary Cortisol
Tremont et al., 2015	USA	250 randomised Gender and age not reported in this paper (Tremont et al. 2013: mean age = 62.72) Intervention n =133 Control n = 117	1 – Family Intervention: Telephone Tracking – Caregiver (FITT-C) 2 – Telephone Support Control (TS)	FITT-C – dementia education, emotional support, directing to resources, self-care promotion, and coping strategies TS – Non-directive support	Both conditions: 16 telephone sessions (First session: 1hr; Follow-up: 15-30mins) over 6 months. Intervention: Summary letter post-intervention.	FITT-C > TS significantly improved depressive symptoms and reduced distress regarding care-recipient depressive behaviours.	ZBI CES-D RMBPC FAD SEQ PAC Euro-QoL

Multi-Component Approach Continued							
Author	**Country**	**Sample**	**Study Arms**	**Manual-Protocol**	**Treatment Length**	**Main Finding**	**Outcome Measures***
Waldorff et al., 2012	Denmark	330 dyads randomised 220 females, 110 males Mean age = 66.0 Intervention n = 163 Control n = 167	1 – Danish Alzheimer Intervention Study (DAISY) multicomponent intervention plus routine follow-up 2 - Routine Follow-up (Control)	DAISY Intervention - (Waldemar et al., 2010) individually tailored for dyads (including counselling, courses, telephone contact) Control – information and guidance (plus facilitated contact to relevant local support programmes)	Intervention: up to 7 counselling sessions, 5 informational courses, telephone contact 5-8 times at 3 or 4 week intervals (8-12 months in total) Control: at 6 and 12 month assessments	No significant differences	GDS EQ-VAS

Psychoeducational Intervention							
Author	**Country**	**Sample**	**Study Arms**	**Manual-Protocol**	**Treatment Length**	**Main Finding**	**Outcome Measures***
Chen, Huang, Yeh, Huang, & Chen, 2015	Taiwan	46 randomised 31 females, 15 males Intervention n = 24 (mean age = 54.8), Control n = 22 (mean age = 55.1)	1 – Psychoeducation intervention 2 – TAU	Intervention: Coping theory based (dementia information, support resources, behaviour management, self-care, problem-solving). TAU – usual clinical care	Intervention: 6 fortnightly home sessions over 3 months	Intervention>TAU: Decreased burden and enhanced use of positive coping strategies (problem-focused and social support).	RMBPC Chinese CBI WCCL-R
Cristancho-Lacroix et al., 2015	France	49 randomised 32 females, 17 males Intervention n = 25 (mean age = 64.2) Control n = 24 (mean age = 59.0)	1 – Web-based intervention 2 – TAU	Intervention - Diapason psychoeducation programme (based on cognitive stress theories, research review, previous study). TAU – dementia information	Intervention: 12 weekly online sessions and access to group forum. Both conditions: follow-up assessment at 3 and 6 months	No significant differences in PSS-14 between groups. PSS scores remained stable despite dementia progression.	PSS-14 RSCSE RMBPC ZBI BDI-II NHP VAS

Psychoeducational Intervention Continued							
Author	**Country**	**Sample**	**Study Arms**	**Manual-Protocol**	**Treatment Length**	**Main Finding**	**Outcome Measures***
Kajiyama et al., 2013	USA	150 randomised, 75 in each group 125 females, 25 males Completers mean age = 56.12 Drop-Outs mean age = 56.17	1 – iCare Condition (ICC) 2 – Education / Information-Only Condition (EOC)	Both web-based plus booklet ICC - Adapted "Coping with Caregiving" (Gallagher-Thompson) Psychoeducation of coping skills to reduce stress. EOC – dementia information.	3-month online course.	ICC > EOC reduced stress. More caregiving effort the less improvement of depressive symptoms. IOC > EOC reduced "bother" about care recipients' behaviour.	PSS RMBPC CES-D PQoL
Livingston et al., 2013	UK	260 randomised 178 females, 82 males Intervention n = 173 (mean age = 62.0) Control n = 87 (mean age = 56.1)	1 – START Intervention (STrAtegies for RelaTives) 2 – TAU	START – Based on "Coping with Caregiving" (Gallagher-Thompson) TAU – Standard treatment in line with NICE clinical guidelines.	Intervention: 8 individual sessions (1 hr) over 8-14 weeks	START > TAU improved QoL and reducing chance of clinical depression at follow-up.	HADS ZBI Modified CTS HSQ Brief COPE

Psychodynamic Therapy							
Author	**Country**	**Sample**	**Study Arms**	**Manual-Protocol**	**Treatment Length**	**Main Finding**	**Outcome Measures***
Kamkhagi et al., 2015	Brazil	37 randomised 27 females, 10 males Intervention n = 20 (mean age = 62.1) Control n = 17 (mean age = 55.7)	1 – Psychodynamic Group Therapy (PGT) 2 – Body Awareness Therapy (BAT) comparison group	PGT – focus on loneliness and helplessness associated with caregiver role, family conflicts, and changing roles within family BAT – Psycho-physiological approach. (Marcia Taques Bittencourt)	Both conditions: 14 weekly group sessions (1.5hr).	No significant differences PGT: significant reduction on burden and depression scores, and improved QoL. BAT: improvements in burden of care and QoL.	ZBI BDI WHO-QoL Scale BAQ

Outcome Measure Terms: Body Awareness Questionnaire (BAQ); Beck Depression Inventory (BDI); Caregiver Burden Inventory (CBI); Center for Epidemiological Studies – Depression (CES-D); Conflict Tactics Scale (CTS); Dysfunctional Thoughts About Caregiving Questionnaire (DTCQ); Experiential Avoidance in Caregiving Questionnaire (EACQ); European Quality of Life Visual Analogue Scale (EQ-VAS); Family Assessment Device (FAD); Giesner Beschwerdebogen (GBB); Geriatric Depression Scale (GDS); Hospital Anxiety and Depression Scale (HADS); Health Status Questionnaire (HSQ); Leisure Time Satisfaction Scale (LTS); Montgomery Borgatta Caregiver Burden Scale (MBCBS); Medical Outcomes Study Social Support Survey (MOSSSS); Nottingham Health Profile (NHP); Neuropsychiatric Inventory – Stress (NPI-S); Neuropsychiatric Inventory – Depression (NPI-D); Positive Aspects of Caregiving Scale (PAC); Positive and Negative Affect Schedule (PANAS); Profile of Mood States (POMS); Perceived Quality of Life (PQoL); Perceived Stress Scale (PSS); Revised Memory and Behavior Problems Checklst (RMBPC); Revised Scale for Caregiving Self-Efficacy (RSCSE); Self-Efficacy Questionnaire (SEQ); Short Form 12 Health Survey (SF-12); Self-Perceived Pressure from Family Care (SPICC); Social Support Scale (SSS); State-Trait Anxiety Inventory (STAI); Visual Analogue Scale (VAS); Revised Ways of Coping Checklist (WCCL-R); Zarit Burden Inventory (ZBI).

**Caregiver outcome measures only.*

symptoms, stress, or negative caregiver experiences) (Cristancho-Lacroix et al., 2015; Losada et al., 2015; Prick, de Lange, Twisk, & Pot, 2015; Tremont et al., 2015; Whitebird et al., 2012); two reported no exclusion criteria relating to mental health (Gonyea, López, & Velásquez, 2016; Waldorff et al., 2012); and one study excluded caregiver participants if they demonstrated evidence of dementia themselves (Livingston *et al.*, 2013).

Intervention

Studies described evaluations of a variety of interventions including specific therapeutic modalities, psychoeducation, and multicomponent approaches. The largest proportion of studies (eight, 57.14%) evaluated interventions based on specific therapeutic modalities and focused on a diverse range of approaches; CBT (Gonyea et al., 2016; Losada et al., 2015; Wilz & Soellner, 2016), Behavioural Activation (BA) (Au, 2015; Moore et al., 2013), Acceptance and Commitment Therapy (ACT) (Losada et al., 2015), Mindfulness-Based Stress Reduction (MBSR) (Whitebird et al., 2012), and Psychodynamic Group Therapy (PGT) (Kamkhagi et al., 2015). Four psychoeducation studies were based on cognitive-behavioural, and stress and coping, theoretical models (Chen et al., 2015; Cristancho-Lacroix et al., 2015; Kajiyama et al., 2013; Livingston et al., 2013). A further three studies included combinations of at least two approaches: counselling, psychoeducation, dementia education, activity scheduling, and emotional support (Waldorff et al., 2012; Prick et al., 2015; Tremont et al., 2015).

Delivery methods of interventions included individual face-to-face (Chen et al., 2015; Livingston et al., 2013; Losada et al., 2015; Moore et al., 2013; Prick et al., 2015), group (Gonyea et al., 2016; Kamkhagi et al., 2015;), telephone (Au, 2015; Tremont *et al.*, 2015), internet based interventions (Kajiyama *et al.*, 2013; Cristancho-Lacroix *et al.*, 2015) and mixed face-to-face and telephone (Waldorff *et al.*, 2012; Whitebird *et al.*, 2012; Wilz & Soellner, 2016). Two multi-component studies recruited care recipients as well as caregivers as dyads and both were present during the delivery of select components of the intervention (Prick et al., 2015, Waldorff et al., 2012).

Duration of intervention, in terms of both overall intervention and session length, varied between studies. Median duration of intervention was 12 weeks (IQR: 12-15 weeks) and ranged from six to 52 weeks. Mean session length was 84.1 minutes and ranged from 15 minutes (telephone contact) to 160 minute sessions. Four studies did not report intervention session time; two were internet based studies (Kajiyama *et al.*, 2013; Cristancho-Lacroix *et al.*, 2015) and two conducted sessions as home visits (Livingston *et al.*, 2013; Chen *et al.*, 2015). One group CBT study involved four additional three-weekly booster telephone 'coaching' calls (Gonyea, López & Velásquez, 2016).

The majority of studies, eight in total, performed follow-up assessments; five conducted this six months post-baseline (Whitebird et al., 2012; Cristancho-Lacroix et al., 2015; Losada et al., 2015; Prick et al., 2015; Wilz & Soellner, 2016), one at three months post-baseline (Gonyea et al., 2016), one at 12 months post-baseline (Moore et al., 2013), and one at eight months post-baseline (Livingston et al., 2013).

Comparison

All studies involved at least one control group. The most common type of control was treatment as usual (TAU) (Waldorff *et al.*, 2012; Livingston *et al.*, 2013; Chen *et al.*, 2015; Cristancho-Lacroix *et al.*, 2015; Prick *et al.*, 2015), minimal support groups (Losada et al., 2015; Moore et al., 2013; Tremont et al., 2015; Whitebird et al., 2012), information or psychoeducation only (Kajiyama *et al.*, 2013; Au, 2015; Gonyea, López & Velásquez, 2016), Body awareness (Kamkhagi *et al.*, 2015) and Progressive Muscle Relaxation or untreated control (Wilz & Soellner, 2016). Two studies reported using three condition arms: CBT, ACT, and minimal support (Losada et al., 2015) and CBT, PMR, and untreated control (Wilz & Soellner, 2016).

Outcomes

Studies tended to measure changes in caregiver distress (e.g. depression, anxiety, burden) more frequently than mental/subjective wellbeing as a measure of intervention efficacy.

A large proportion of studies (85.71%) measured carer depression and the most widely used measure was the CES-D (75.00%). Reduction in reported depression symptoms were observed across most intervention types compared to controls: CBT (Gonyea et al., 2016; Losada et al., 2015), ACT (Losada et al., 2015), MBSR (Whitebird e al., 2012), BA (Moore et al., 2013; Au, 2015), psychoeducation (Livingston et al., 2013), and multicomponent interventions (Tremont et al., 2015). However, the psychoeducation study reported a small effect size (Livingston et al., 2013). One study of a multicomponent intervention reported that conversely depression symptoms increased during the intervention (Prick et al., 2015). No significant differences in depression scores compared with control groups were observed by three studies: PGT (Kamkhagi et al., 2015), online psychoeducation (Kajiyama et al., 2013) and multicomponent (Waldorff et al., 2012) interventions);

Four studies (28.57%) measured the outcome of interventions by changes in anxiety levels, using three different measures. Reduced anxiety was significant following psychoeducation compared with control (Livingston et al., 2013). Losada and collegues (2015) reported a greater reduction in anxiety symptoms following ACT rather than CBT or control. This was also the case with MBSR and minimal support (education, emotional and social support) (Whitebird et al., 2012). Another study also reported no difference in anxiety between CBT and control group (Gonyea et al., 2016).

Three studies (21.43%) measured caregiver stress levels, all utilised the Perceived Stress Scale. Significant between-group stress reduction was reported following MBSR (Whitebird et al., 2012) and psychoeducation interventions (Kajiyama et al., 2013). However, Cristancho-Lacroix and colleagues (2015) found no significant differences between an online psychoeducation intervention and control group.

Caregiver burden was measured by six studies (42.86%) using several different measures. Decreased burden was observed compared to control group for one psychoeducation intervention (Chen et al., 2015). However, no between-group difference in caregiver burden was reported for PGT (Kamkhagi et al., 2015) or following MBSR (Whitebird et al., 2012). One CBT study reported a significant but small effect on reduced distress about the behaviours of the care recipient following CBT compared to control (Gonyea et al., 2016), however, two further studies reported no significant between-group differences for multicomponent (Tremont et al., 2015), or psychoeducation (Kajiyama et al., 2013) interventions.

Wellbeing of caregivers was measured by seven studies (50.00%) using diverse measures (QoL, emotional wellbeing, self-efficacy, social support). Quality of life improved post intervention for individual psychoeducation-based therapy (Livingston et al., 2013), however no differences were observed for PGT (Kamkhagi et al., 2015), online psychoeducation (Kajiyama et al., 2013) or multicomponent (Waldorff et al., 2012) interventions. Other aspects of wellbeing were shown to increase post CBT including a moderate effect size for emotional wellbeing (Wilz et al., 2016) and very small effect size for self-efficacy (Gonyea et al., 2016). Social support, as measured by a single study, did not differ significantly post MBSR intervention (Whitebird et al., 2012).

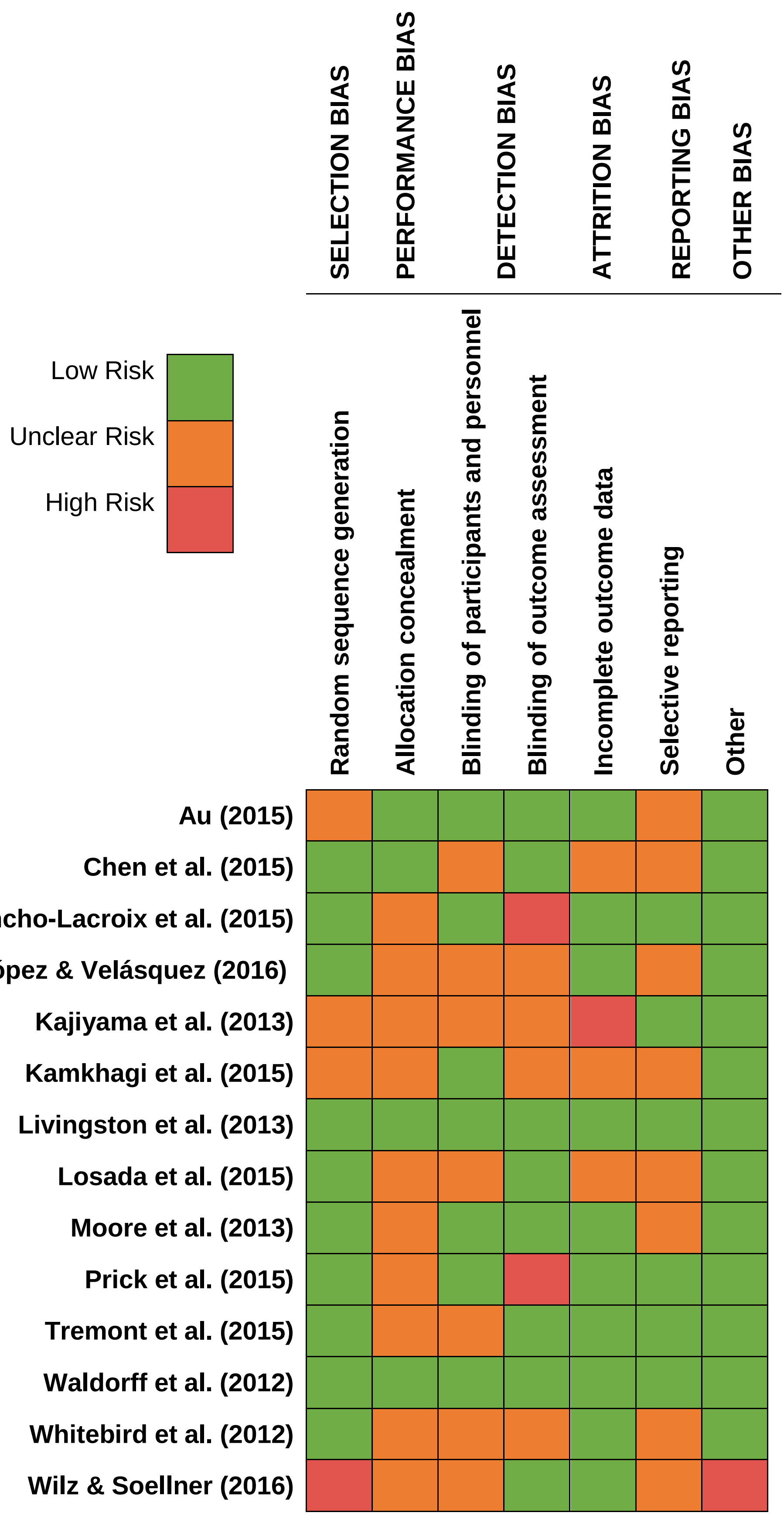
Four studies reported the maintenance of effects compared with control groups. CBT was reported to have durable effects on depression (Losada *et al.*, 2015; Gonyea, López & Velásquez, 2016) and self-efficacy (Gonyea, López & Velásquez, 2016) at follow-up. Overall improvements in mental health were maintained at 6-month follow-up for MBSR (Whitebird *et al.*, 2012). Improvements in perceived health at 6-month follow-up were significant compared with the untreated control group (Wilz et al., 2016). No significant difference in depression between BA and control group was observed over one year (Moore et al., 2013). No protective effects on anxiety or depression were observed at follow-up for ACT (Losada *et al.*, 2015) or coping-based intervention (Livingston *et al.*, 2013) compared with control group. Four studies did not investigate effects of treatment at long-term follow-up (Au, 2015; Chen *et al.*, 2015; Kamkhagi *et al.*, 2015; Tremont *et al.*, 2015).

Risk of Bias Assessment

In general risk of bias across the fourteen studies assessed was variable and a high proportion (85.71%) had at least one area evaluated to be ‘unclear’. Figure 2 outlines the distribution of scores across the studies reviewed. Two studies received scores of ‘low bias’ for all seven areas assessed (Waldorff *et al.*, 2012; Livingston *et al.*, 2013). The areas of the lowest bias across all articles reviewed were in the domains of randomisation and attrition bias; most studies reported this to a satisfactory level and the methods reported are likely to have prevented additional bias from occurring within these aspects.

Five scores of ‘high’ bias were awarded across four studies; one for randomisation, one for attrition bias, two for blinding of outcome assessment, and one for ‘other bias’. The most common areas of bias were allocation concealment (10 studies [66.7%]) scored ‘unclear’ and was mostly due to articles not including details of the methods involved in this process. One study was scored as having high ‘other’ bias due an additional non-randomised arm with associated systematic group differences (i.e. based on geographical location) and subsequent data handling of

Figure 2. Risk of Bias Assessment



Low Risk 🟩
Unclear Risk 🟧
High Risk 🟥

	SELECTION BIAS		PERFORMANCE BIAS	DETECTION BIAS	ATTRITION BIAS	REPORTING BIAS	OTHER BIAS
	Random sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment	Incomplete outcome data	Selective reporting	Other
Au (2015)	🟧	🟩	🟩	🟩	🟩	🟧	🟩
Chen et al. (2015)	🟩	🟩	🟧	🟩	🟧	🟧	🟩
Cristancho-Lacroix et al. (2015)	🟩	🟧	🟩	🟥	🟩	🟩	🟩
Gonyea, López & Velásquez (2016)	🟩	🟧	🟧	🟧	🟩	🟧	🟩
Kajiyama et al. (2013)	🟧	🟧	🟧	🟧	🟥	🟩	🟩
Kamkhagi et al. (2015)	🟧	🟧	🟩	🟧	🟧	🟧	🟩
Livingston et al. (2013)	🟩	🟩	🟩	🟩	🟩	🟩	🟩
Losada et al. (2015)	🟩	🟧	🟧	🟩	🟧	🟧	🟩
Moore et al. (2013)	🟩	🟧	🟩	🟩	🟩	🟧	🟩
Prick et al. (2015)	🟩	🟧	🟩	🟥	🟩	🟩	🟩
Tremont et al. (2015)	🟩	🟧	🟧	🟩	🟩	🟩	🟩
Waldorff et al. (2012)	🟩	🟩	🟩	🟩	🟩	🟩	🟩
Whitebird et al. (2012)	🟩	🟧	🟧	🟧	🟩	🟧	🟩
Wilz & Soellner (2016)	🟥	🟧	🟧	🟩	🟩	🟧	🟥

randomised and non-randomised group data (i.e. combined during analysis) (Wilz et al., 2016). Seven studies (50.00%) had 3 or more ‘unclear’ bias scores and over a third of domains across all studies received a score of ‘unclear’ (36 out of 98 [34.69%]). Generally, this was due to a lack of reporting on specific practice methods and clarity about access to original study protocol aims.

DISCUSSION

Dementia is a considerable global issue with the potential for substantial impact on the wellbeing of those who care for people with this diagnosis. This current review updated and adapted a previous systematic review of psychological interventions for CPwD (Elvish et al., 2013). Fourteen RCT evaluations of a variety of psychological interventions were published over the past five years; including diverse psychotherapies, psychoeducation, and multicomponent approaches. Although this represents a similar figure to previous reviews (Elvish et al., 2013; Gallagher-Thompson & Coon 2007), both a narrower timeframe and search focus was adopted during this current review and therefore presents an indication of evidence-base growth within this research area; particularly apparent was the immergence of new applications of psychotherapeutic (ACT, MBSR, PGT) and internet-based approaches with this population. Delivery type of intervention (e.g. individual or group, face-to-face or online) was considered a separate factor in this review, a further divergence from the approach taken by Elvish and colleagues (2013) who reported separately on ‘technology based studies’ including only telephone-based interventions.

Reported outcomes suggest that CBT may be effective for reducing, and maintaining reduction in, depression symptoms (Losada et al., 2015; Gonyea et al., 2016; Wilz et al., 2016) distress related to care recipient behaviour (Gonyea et al., 2016), and increased wellbeing (Wilz et al., 2016; Gonyea et al., 2016). ACT may significantly improve depression and anxiety symptoms post-treatment compared with minimal support group (Losada et al., 2015). MBSR appeared to improve carer stress and depression compared to the control condition (Whitebird et al., 2012). BA appeared to improved depression compared with control conditions (Au, 2015) but this was not maintained over time (Moore et al, 2013). Psychoeducation interventions, based on cognitive-behavioural principles, demonstrated significant decreases in carer anxiety and quality of life, depression (Livingston et al., 2013), stress (Kajiyama *et al.*, 2013), and burden (Chen et al., 2015). One multicomponent intervention reported higher depression reduction compared with the control arm (Tremont et al., 2015). Caregiver participants were recruited from clinical and non-clinical populations (some with required baseline distress levels).

Risks of bias were identified in most studies and commonly resulted from a lack of clarity around procedures used to conceal allocation and blind participants and researchers to study conditions. These are areas which are challenging for psychotherapy trials to address due to the nature of this type of intervention; however, the potential impact of this should be acknowledged when considering future application of results. By contrast, most studies randomisation and incomplete data handling practices were likely to have presented a low risk of bias. Variation in overall risk of bias of the studies evaluated highlights the importance of considering these limitations when interpreting and generalising RCT results.

Limitations of Current Review

The decision to limit search criteria solely to include RCT designed studies provided a focussed assessment and enabled risk of bias evaluation; however, the breadth of developing evidence of psychological therapies acceptability and effectiveness is unlikely to be fully represented. Similarly, by excluding qualitative design methods, information about carer experience and intervention acceptability is missing from this review. Despite researchers attempts to identify mechanisms of action of interventions, further information regarding the process of change would be beneficial for enhancing understanding of efficacy with CPwD populations.

Recommendations and Conclusions

Exploration and assessment of the RCT articles presented in this review has raised some key methodological recommendations for future research conducted in this area. There appears to be a good variety of research interest across different therapeutic modalities and methods of delivery. Replication studies of less frequently researched interventions would strengthen the impact of this emerging evidence base. Further information about the efficacy of key components of psychotherapies for CPwD may facilitate future exploration and interpretation of results.

Researchers demonstrated a tendency to report alterations in caregiver depression symptoms and, whilst a valid hypothesis to measure, the complex psychological interactions of caring for someone with dementia merit further investigation. Some studies measured positive improvements, as well as reduced negative symptoms, and the most recent study explicated emotional wellbeing. In general, researchers used a wide range of assessment tools to measure a range of outcomes which may affect the ability to draw comparisons between results. Future research could be enhanced by using standardised assessment measures of mental health and wellbeing.

Risk of bias was apparent across most studies reviewed and a significant proportion of ‘unclear’ scores were due to insufficient or inaccessible published methodological details. Guidelines such as the Cochrane Risk of Bias Tool (2011) may support researchers during the design and dissemination stages of RCT intervention studies. Psychological interventions for CPwD is a rapidly growing research domain with an expanding scope of interest. This review demonstrates recent developments including a shift in focus of therapeutic modality and delivery methods. Methodological and reporting improvements highlighted would potentially increase the impact and future availability of effective interventions to promote the wellbeing of carers of people with dementia.

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Chapter Two: A Feasibility Study of Acceptance and Commitment Therapy to Promote the Wellbeing of Carers of People with Dementia

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Plan English Summary

Background: Carers of people with dementia may experience poor mental wellbeing associated with their role. Some people also report finding meaning in their experience and describe caring as rewarding. Those whose wellbeing is greater are said to be ‘flourishing’ (Keyes, 2002).

Acceptance and Commitment Therapy (ACT) is a therapy that helps people to notice and accept difficult thoughts and emotions rather than trying to eliminate or change them. ACT also helps people to identify what they value in life (e.g. a good relationship with their partner) and make changes to their behaviour to engage in actions consistent with these values (Hayes *et al.*, 2006).

Study Aims: This study aimed to evaluate the feasibility of running an ACT group for carers of people with dementia. Feasibility studies are an important first step in assessing the viability of research topics. The research aimed to answer the following key questions:

1. Did people attend the group?
2. Were those who attended satisfied with the group?
3. What parts of the group did people find helpful?
4. Did the questionnaires we used to evaluate the group tell us what was improved?

What the Study Involved: Participants included adult carers of people with dementia. Individuals were ineligible if they were receiving another therapy at the time of first meeting with the researcher. Study participants were recruited from two older people community mental health teams. Participants attended one or other of two groups; both groups attended three 2.5 hour sessions of ACT. All participants were asked to complete five questionnaires at the beginning and end of the groups (asking questions about their wellbeing, thoughts, feelings, and about being a carer). Eight group participants were invited to a discussion group to understand more about their experience of the ACT group.

Research ethics approval was granted before the study started (Ref: 16/WS/0240). Informed consent was sought from all participants. All questionnaires and study data are kept safe and secure.

Results: Eighteen participants were recruited (group 1 = 12, group 2 = 6) and thirteen attended all three group sessions (group 1 = 10, group 2 = 3). Reasons reported for not attending all three sessions included having health problems and other caring commitments. Results provided signs that the group improved wellbeing, particularly in the social domain. This was supported by responses provided by participants during a discussion group following the ACT group completion: e.g. participants reported feeling reassured and connected.

Conclusions: The results from this study support the potential utility of ACT groups for carers of people with dementia. The outcomes of this study are encouraging but it would be necessary to conduct a further study with more participants. Future research might also consider what specifically about this group may be of benefit for carers of people with dementia.

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ABSTRACT

Background

Caring for a person with dementia is thought to increase the likelihood of experiencing reduced emotional, social and psychological wellbeing. It is therefore important to consider what types of support may be beneficial. Emerging evidence suggests that Acceptance and Commitment Therapy (ACT) may have positive effects on individuals' subjective wellbeing. To date, the potential efficacy of ACT for enhancing subjective wellbeing in carers of people with dementia has not been fully explored.

Aims

The primary focus of this study was to evaluate the feasibility of delivering an ACT group for caregivers of people with dementia. Study aims were investigated using the PICO framework (Population, Intervention, Control, Outcome) and included questions regarding recruitment, retention, intervention fidelity, acceptability and signs of efficacy.

Method

A mixed methods uncontrolled feasibility trial design was used. The ACT group was delivered over three 2.5-hour sessions at two different sites. The following outcome measures were administered at baseline and at the end of the final session: Mental Health Continuum - Short Form, Acceptance and Action Questionnaire - II, Experiential Avoidance in Caregivers Questionnaire, and the Caregiver Burden Scale. Acceptability of the intervention was measured using a semi-structured group interview and evaluation questionnaire.

Results

Recruitment, although successful, highlighted challenges for services and service users. Eighteen participants were recruited (group 1 = 12, group 2 = 6) and over one quarter of participants did not attend all three groups (group 1 = 2, group 2 = 3) due to poor physical health and caring duties. The group was delivered with fidelity to the ACT model. Group participation was associated with increased levels of overall subjective wellbeing, particularly social wellbeing. No significant changes were observed in terms of emotional or psychological wellbeing, psychological flexibility or burden. Overall, participants declared the group to be acceptable and useful.

Conclusions

There is a need to improve support options for carers of people with dementia. Larger scale studies (e.g. RCTs) might continue to explore the efficacy and change mechanisms of ACT interventions for this population. Optimisation of the group delivery (e.g. session quantity) would be useful as part of future intervention development.

INTRODUCTION

Carer Wellbeing

Dementia and its impact has been widely researched and documented from social, political, financial, and healthcare perspectives. Latest UK figures estimate that 850,000 people are currently living with dementia and at least 670,000 people provide informal care (Alzheimer's Society, 2014). Reduced wellbeing of both individuals with dementia and their caregivers has been considered the greatest impact of dementia (World Alzheimer Report, 2016).

Becoming a carer of someone with dementia represents a significant and dynamic stressor that has the potential to provoke diverse reactions over time. Research into the common impacts of wellbeing that carers of people with dementia (CPwD) experience is developing and thought to include increases in burden, depression, stress, and social isolation (Burns & Rabbins, 2000; Sörensen *et al.*, 2006; Neil and Bowie, 2008). Despite significant personal impacts that CPwD face some evidence suggests the potential for positive contributions to wellbeing associated with acceptance of the role; satisfaction, emotional reward, and fulfilment (Tarlow *et al.*, 2004; Lloyd, Patterson & Muers, 2016).

Improving Carer Wellbeing

Evidence regarding the efficacy of wellbeing interventions for CPwD is developing and many studies tend to focus on reducing negative psychological effects of caregiving. Most interventions are based on the assumption that reducing mental health concerns (e.g. depression, stress, and burden) improves carer wellbeing yet effect sizes tend to be "weak to moderate" (Zarit & Femia, 2008). A recent review reported that psychological interventions developed from cognitive behavioural approaches were effective at reducing distress for CPwD (Elvish *et al.*, 2013). Generally, levels of distress were used as indicators of intervention efficacy, however, two of the 17 studies identified measured wellbeing using adapted non-validated measures and reported improvements following psychoeducational interventions; self-efficacy (Stern *et al.*, 2008), emotional wellbeing and quality of life (Perren, Schmid & Wettstein, 2006).

Acceptance and Commitment Therapy for Carers

Acceptance and Commitment Therapy (ACT), a 'third wave' cognitive behavioural therapy, aims to increase psychological flexibility through experiential mindful-acceptance and values-based behaviour change processes (Hayes, Strosahl & Wilson 2006). ACT is distinct from other types of cognitive behavioural therapy as it does not aim to change the content of thoughts per se, instead seeking to change an individual's relationship to their thoughts so that the person can engage in 'value-consistent' behaviour, to improve wellbeing. 'Psychological flexibility', a purported mechanism of change for ACT, is the ability to contact the present moment in an open and accepting way and engage in behaviours that are consistent with personal values. Conversely, psychological *inflexibility* is thought to underpin many emotional and behavioural difficulties (Hayes *et al.*, 2006). Recent research has also demonstrated that ACT interventions can lead to increased levels of subjective wellbeing ('flourishing') for Dutch adults with mild to moderate depressive symptoms (Bohlmeijer, Lamers & Fledderus, 2015). This highlights a need to explore associations between 'flourishing' and psychological flexibility further and to assess the impact that ACT interventions can have on specific components of subjective wellbeing.

Recent meta-analyses of ACT studies demonstrate that, as a transdiagnostic model, ACT is effective compared with standard treatment across a wide range of clinical and non-clinical populations (Powers, Zum Vörde Sive Vörding & Emmelkamp, 2009; Ruiz, 2010; Öst, 2014). ACT has been demonstrated to reduce distress when delivered to carers of people with brain injury (Williams *et al.*, 2014), intellectual disabilities (Noone & Hastings, 2010), and children with autism (Blackledge & Hayes, 2006). Psychological inflexibility has also been shown to be positively correlated with distress for CPwD (Losada, Márquez-González & Romero-Moreno, 2014).

ACT interventions for CPwD have been solely investigated/published by one Spanish research group. A non-randomised controlled pilot of a group-based ACT intervention for CPwD demonstrated significant increases in psychological flexibility (Márquez-González, Romero-Moreno, & Losada, 2010). A subsequent RCT, comparing individual ACT and CBT for CPwD experiencing depression, also reported significantly increased psychological flexibility and reduced anxiety unique to the ACT condition (Losada *et al.*, 2015). The third control arm used a different mode of intervention (group-based) and participants were selected for high depression scores; limiting interpretation of the treatment effects and generalisability.

Mental Health and Mental Wellbeing

Comparable with concepts surrounding physical health and physical illness, recent theories have proposed that mental health and mental illness also form separate continua (Westerhof & Keyes, 2010). This is consistent with WHO definitions of mental health that emphasises not merely an absence of mental illness but also the presence of mental wellbeing (WHO, 2013). This has provoked research interest into subjective wellbeing definitions and its distinct components. Mental wellbeing has been explored and developed as a concept for several years within positive psychology research. The term ‘flourishing’ has been used to describe a state of mental health that encapsulates an individual experience of emotional, psychological, and social wellbeing (Keyes & Haidt, 2003); the Mental Health Continuum questionnaire, developed by Keyes (2002), was developed as a method of operationalising and measuring these dimensions.

Current Study

Based on the developing evidence it seemed plausible that an ACT group intervention would be acceptable and useful for CPwD. Conducting significant development and pilot work has been recognised as an important initial stage of evaluating complex interventions (Medical Research Council, 2008). Feasibility objectives were constructed using the PICO framework, aimed at characterising recipient Population, Intervention parameters, potential Control conditions, and meaningful Outcomes (Oxman, Sackett & Guyatt, 1993; Richardson *et al.*, 1995).

Aims and Hypotheses

This project aimed to evaluate the feasibility of delivering an ACT intervention to promote the subjective wellbeing of CPwD. Determining a comparator was not considered a relevant goal because of the preliminary nature of the study. The focus of the study was to investigate the following research questions:

Population:

a) What number of participants identified fulfil eligibility criteria?
b) What proportion of participants provide fully informed consent to participate in the study?
c) What are participants’ baseline levels of wellbeing, psychological flexibility, and burden?

Intervention:

d) Will the intervention be acceptable to CPwD?
    1. What proportion of participants are retained throughout the intervention?
    2. What feedback do participants provide regarding their experiences of the group?

e) Can the intervention be delivered with fidelity?

Outcomes:

f) What differences occur between pre- and post-intervention measures of wellbeing, psychological flexibility, and burden?
g) How effective do participants evaluate the group to be?
h) What are the rates of retention at follow-up?
i) Are there identifiable features of participants that drop out or are lost to follow-up?

METHODS

Design

An uncontrolled feasibility design was employed using a feasibility driven mixed methods approach; exploring the feasibility of delivering, evaluating, and identifying key processes of the ACT intervention with this novel population.

Participants

Participants were eligible if they were adult primary caregivers of a person who had received a diagnosis of dementia at least 3 months prior to recruitment. Carers were not recruited if they could not consent to participate, experiencing severe or acute mental health problems, were receiving concurrent psychotherapy or were not proficient in English.

Ethical Approval

Research procedures were approved by the West of Scotland NHS Research Ethics Service Committee No. 3 (ref: 16/WS/0240) and R&D approval (ref: GN16MH672) was authorised by NHS Greater Glasgow and Clyde (Appendix 2.2).

Procedure

Recruitment

Participants were identified by clinicians at two Older People's Community Mental Health Teams within NHS Greater Glasgow and Clyde health board and provided with patient information sheets including 'opt in' slips. Interest was expressed by participants by completing the 'opt in' slip and consent given for their contact details to be provided to the researcher, who telephoned carers and posted invitation letters. Informed consent was obtained at enrolment in the study. The two intervention groups took place sequentially over two months following a recruitment period of a month at each site.

ACT Group Protocol

The ACT group was a manualised intervention modified from the "two-plus-one" protocol developed by Paul Flaxman and colleagues (Flaxman, Bond & Livheim, 2013; Lloyd *et al.*, 2013). The ACT intervention consisted of three group sessions (2.5 hours per session): two sessions delivered on consecutive weeks followed by one session two weeks later (Appendix 2.3). The main researcher and a qualified Clinical Psychologist from the respective mental health team co-facilitated the groups. ACT training and regular supervision was provided by *ACBS Peer Reviewed ACT Trainer* Dr Ross White. All sessions were audio recorded and were randomly assigned for ACT model fidelity assessment by two senior researchers who used the ADAPT Therapist Fidelity and Competence Scale Version 2.2 developed by Dr Ross White and colleagues (Appendix 2.7).

Data Collection

Measures were completed at baseline prior to the first session and repeated post-baseline after the third session. A demographics questionnaire was completed at baseline and an acceptability questionnaire was completed by participants at the post-baseline timepoint. Baseline measures and demographic questionnaires were posted to participants together with an invitation letter and were handed to the facilitators at the start of the first group session. Post-baseline measures and acceptability questionnaires were completed at the end of the third session in the same room as the group was held and in the presence of facilitators.

A pre-determined figure of 33% attrition from baseline to final assessment was used to indicate intervention acceptability (Lambert & Ogles, 2004). Participants from both groups, who had completed the intervention, were invited at the end of the final session to attend a focus group scheduled two or six weeks after the last ACT session. Focus groups have been suggested to be the ideal method for assessing intervention acceptability (Bowen *et al.*, 2009). An independent researcher used a semi-structured interview schedule focussing on the acceptability of the study to guide the session (Appendix 2.4). The focus group session was audio-recorded, transcribed and anonymised.

Measures

Primary outcomes were the feasibility of recruitment, retention, intervention fidelity and acceptability. An acceptability questionnaire, including Likert scale and free-text response questions, was used to evaluate participants' experience of the intervention (Appendix 2.5). Demographic data were collected to provide study population characteristics. Outcome measures were used to evaluate indications of treatment signals and potential mechanisms of change.

Mental Health Continuum - Short Form (MHC-SF; Keyes, 2002) is a 14-item questionnaire measuring wellbeing (emotional, social, and psychological) in terms of the presence and absence of mental health i.e. levels of 'flourishing' and 'languishing' respectively. Respondents are asked to assess how many times they felt a certain way (e.g. 'interested in life') on a six-point Likert scale. This scale has sound internal consistency (α=0.89) and 3 and 9-month test-retest reliability of 0.65 (Lamers *et al.*, 2011). Total scores range from zero to 70; clinical scores are termed 'languishing' and require a score of one or less on at least one of the first three items and a score of one or less on at least six of the next eleven items.

Acceptance and Action Questionnaire-II (AAQ-II; Bond *et al.*, 2011) is a 7-item questionnaire that measures psychological inflexibility as an ACT outcome. Respondents are asked to rate the truth of each statement (e.g. 'I'm afraid of my feelings') on a seven-item Likert scale. An acceptable internal consistency (α=0.84) and 3 and 12-month test-retest reliability 0.81 and 0.79 were found. Total scores range from seven to 49 and higher scores represent increased psychological inflexibility; a score above 24-28 is considered to represent clinical relevant distress

Experiential Avoidance in Caregiving Questionnaire (EACQ; Losada, Márquez-González & Romero-Moreno, 2014) is a 15-item questionnaire measuring psychological inflexibility. It was developed and evaluated specifically with dementia caregivers. Respondents rate how true each statement is (e.g. ‘I cannot bear it when I get angry with my relative’) on a five-item Likert scale. Acceptable mean internal consistency of was reported (α=0.70). Total scores range from five to 75 and higher scores represent increased psychological inflexibility; clinical cut-off scores have not yet been established.

Caregiver Burden Scale (CBS; Zarit et al. 1980) is a 22-item questionnaire measuring the overall level of burden carers experience in relation to their relative. Respondents are asked to rate how often they identify with each statement across 6 subsections (e.g. ‘Overtaxed with responsibilities) on a five-item Likert scale. Good mean internal consistency (α=0.89) is reported for this scale (Zarit, Antony & Boutselis, 1987). Total scores range from zero to 88 and higher scores represent increased burden; clinical cut-off is considered to be a score greater than 40.

Sample Size

Prospective power calculations were not completed as effect sizes were unavailable due to the preliminary status of this area of investigation. The outcomes of this feasibility study attempt to provide additional information regarding sample size estimations for future research.

Data Analysis

Quantitative

Descriptive statistics provide information regarding baseline demographic and psychological profiles of participants. Recruitment, retention and outcome measure completion rates are reported and together with acceptability questionnaire results provide indications of feasibility. Associations between baseline measures were assessed using Spearman’s Rho correlation co-efficient (two-tailed); Bonferroni corrections were used to reduce Type 1 error risk at p=0.008 level.

Indicators of intervention efficacy were explored using two methods: inferential statistical and sensitivity analysis. Treatment signals were analysed initially using Wilcoxon Signed Rank and Fischer’s Exact Tests due to violations of normality. Further sensitivity analyses were performed as reporting statistical significance of change scores is not generally indicated for feasibility studies. Rather than statistical significance, a focus on clinical significance was implemented. Clinical significance, describing meaningful individual clinical change, was considered reached if change scores meet the following criteria (Jacobson & Truax, 1991):

1. Reliable as per the Reliable Change Index (RCI): < -1.96 or >1.96
2. Scores are above clinical cut-off at baseline to below clinical cut-off at post-baseline.

Published psychometric information provided both reliability and clinical-cut off scores for all scales used (see above 'Measures' section).

Mann Whitney U and Fischer's Exact analyses were used, due to normality violations, to identify differences between participants who did and did not complete the intervention.

Qualitative

Focus group data were analysed using a Framework Analysis approach involving the following standard steps: 1. Familiarisation, 2. Identifying a thematic framework, 3. Indexing, 4. Charting, 5. Mapping and interpretation (Ritchie & Spencer, 1994). This method facilitates the discovery of themes within pre-determined over-arching concepts (i.e. acceptability). It has been particularly recommended as a useful approach when evaluating interventions (Newbold, Hardy & Byng, 2013) and managing the large quantity of data that is produced by focus groups (Rabiee, 2004). The process of analysis was iterative and involved the emergence and integration of themes that were not initially predicted. Finalised themes were ratified by an independent reviewer and consensus reached through discussion.

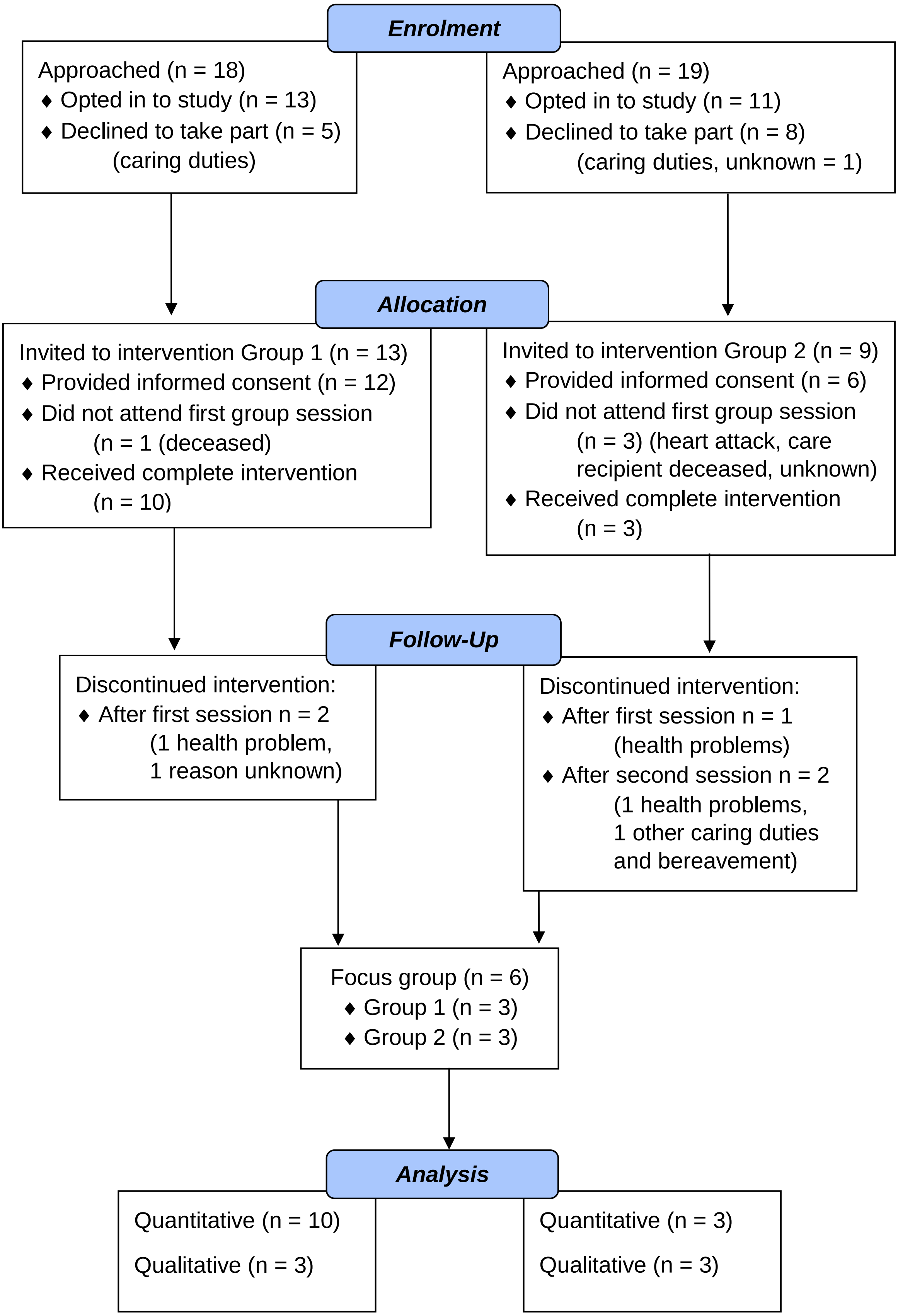
RESULTS

Quantitative Results

Recruitment and Retention

A total of 18 carers of people with dementia provided fully informed consent to participate in the study (group 1: n = 12, group 2: n = 6); out of 37 who were approached and provided with information regarding the study across the two sites. Figure 1 outlines the recruitment process; including the proportion of potential participants expressing interest who subsequently consented to participate in the intervention (75%: group 1 = 92.31%, group 2 = 54.55%).

Figure 1. Consort 2010 Flow Diagram: Frequencies of referrals, assessments, recruitment, attendance, and retention



Population

Table 1 details the demographics of the study sample of participants. Dementia diagnosis was not collected formally, however, the sample included recipients of care who had a variety of dementia diagnoses including Alzheimer’s, Vascular and Unspecified Dementia. Baseline levels of wellbeing, psychological flexibility, and carer burden are reported in table 2. There was variation in terms of the psychological profile of participants; average scores suggested that participants experienced overall ‘moderate mental health’ and across specific domains of wellbeing (MHC-SF; Lamers *et al.*, 2011), below ‘clinically relevant distress’ for psychological flexibility (AAQ-II cut-off range 24-28; Bond *et al.*, 2011) and ‘moderate-severe’ carer burden (CBS cut-off ranges ‘Moderate-Severe’=41-60, ‘Severe’=61-88; Stagg & Larner, 2015). No clinical cut-off scores were available for the EACQ.

Table 1. Demographic Information

	All Participants (n = 18)
Mean Age (Years (SD)	67.13 (7.59)
Gender (Female) (%)	12 (66.67)
Ethnicity (White British) (%)	18 (100.00)
Employment (%)	
Employed	4 (22.22)
Retired	11 (61.11)
Unemployed	2 (11.11)
Unknown	1 (5.56)
Relationship (%)	
Spouse/Partner	12 (66.67)
Adult Child	5 (27.78)
Mean Duration of Caring Role (Months (SD)	32.38 (22.39)
Time Caring (Days per week) (%)	
<1	1 (5.56)
1-3	1 (5.56)
4-6	8 (44.44)
Most (some breaks)	3 (16.67)
All (no breaks)	4 (22.22)
Other Caring Duties (%)	3 (16.67)

Table 2. Participant baseline psychological profile mean scores (mental health, psychological flexibility, burden)

	TOTAL (n = 16)
MHC-SF (SD)	39.75 (15.49)
Emotional Wellbeing	9.25 (3.80)
Social Wellbeing	11.62 (6.11)
Psychological Wellbeing	18.88 (7.23)
Flourishing (%)	5 (31.25)
Moderately Mentally Healthy (%)	8 (50.00)
Languishing (%)	3 (18.75)
AAQ-II (SD)	23.19 (11.01)
EACQ (SD)	36.94 (10.12
CBS (SD)	42.75 (21.58)

Associations between outcome measures at baseline are detailed in Table 3. MHC-SF scores were significantly negatively correlated with AAQ-II scores (r = -0.741, p = 0.001) and CBS scores (r = -0.749, p = 0.001). The CBS scores also had a significant positive correlation with the EACQ (r = 0.688, p = 0.003) and AAQ-II (r = 0.653, p = 0.006) scores. The AAQ-II and EACQ scores were positively correlated (r = 0.518, p = 0.04).

Table 3. Spearman's rho (ρ) correlations between baseline outcome measures

Measures	**MHC-SF**	**AAQ-II**	**EACQ**
AAQ-II	-0.741***		
EACQ	-0.462	0.518*	
CBS	-0.749***	0.653***	0.688***

** Correlation significant at 0.05 level (2 tailed) ** Correlation significant at 0.01 level (2-tailed) *** Correlation significant at 0.008 (Bonferroni correction)*

Missing Data

Missing data provided information about the feasibility of evaluating the intervention and highlighted potential issues with using specific measures. Data were missing or incomplete for eight participants (44.44%); two did not complete full baseline assessments, three missed items from baseline questionnaires, and three missed or did not complete significant sections of follow-up questionnaires.

Two participants did not complete demographic information or outcome measures at baseline although information such as gender, ethnicity, and relationship with care recipient was available. One participant did not bring the questionnaires with them and subsequently dropped out. The other participant did not believe they were suitable for the group and did however complete post-baseline measures.

Five participants completed the majority of outcome measures but missed particular items or sections of questionnaires:

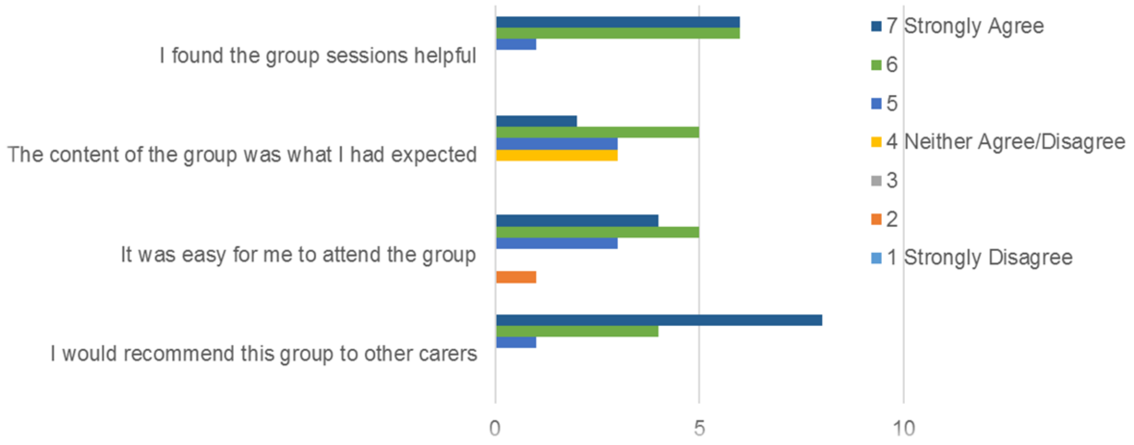
- MHC-SF: Item 7 was incomplete for one participant at baseline who wrote a comment describing their experience instead. This participant also did not complete this follow-up questionnaire. Items 7 and 9 were scored twice by one participant at baseline. One participant missed item 8 at follow-up. Item 7 and 8 both measure social wellbeing and 9 measures psychological wellbeing. A fourth participant did not complete the follow-up questionnaire.
- AAQ-II: No missing questionnaires or items.
- EACQ: Item 4 was missing for one participant at baseline. One participant did not complete twelve items at follow-up.
- CBS: Items 4 and 6 were missing for one participant at baseline. Items 10 and 16-21 were not completed by a participant at follow-up due to the perceived relevancy to their situation. In addition, a proofing error occurred during the development of the outcome measures which resulted in missing item 22 at baseline and follow-up.

Single missing items were imputed using individual participant mean item scores on relevant questionnaires. Highest scores were used where participants scored items twice. Data were not included in analysis where substantial sections of questionnaires were incomplete. Baseline scores were carried forward for clinical change calculations.

Acceptability of ACT Group Intervention

Overall, 72.22% of participants received the full intervention (n = 13: 83.33% in group 1; 50.00% in group 2) (Figure 1). The intervention appeared to be evaluated as acceptable to participants as suggested by acceptability questionnaire responses completed by all participants (Figure 2). One participant who attended two sessions also provided feedback.

Figure 2. Participants Acceptability Questionnaire Response Frequencies



All participants reported finding the group helpful in terms of content and delivery (Appendix 2.6). Participants highlighted the mindfulness components of the intervention as especially useful: *"Mindfulness exercises helped me deal with my thoughts and feelings"* (participant 6). Values-based group experiences (including use of analogy and promoting self-care) were also reported as helpful: *"Raising awareness of self-helping"* (participant 5). Participants described satisfaction of sharing experiences in the group: *"It was great to be able to be part of a group where the others shared similar experiences to oneself"* (participants 8).

Recommendations for improving acceptability included having *"Longer sessions to fully get into the exercises"* and *"Perhaps extending the length of the course would be beneficial"* (participants 1 and 5). Participants suggested improving the method of evaluation *"Maybe time to think and evaluate (Stamped Addressed Envelope)"* and the physical environment *"Could have been improved with a 'horseshoe' desk arrangement"* (participants 17 and 1).

Fidelity

Assessors reported that the intervention was delivered with fidelity to the ACT model approach. Evidence of the transmission of key therapeutic concepts was present, however assessment of individual member receptiveness to therapeutic messages was challenging in a group format (Appendix 2.7).

Outcomes and Treatment Signals

Significant differences between baseline and post-baseline overall wellbeing and social wellbeing specifically were observed for those who completed the ACT group intervention. A significant association between level of flourishing pre- and post-baseline was also observed; two participants who were 'languishing' at baseline were subsequently 'moderately mentally health' and one person 'moderately mentally healthy' at baseline was 'flourishing' at follow-up. There were no significant changes identified in terms of participants' psychological flexibility or carer burden. Table 4 provides an overview of outcome measure data changes between baseline and post intervention.

Table 4. Changes in scores between baseline and post-intervention mean scores (n = 12)

	Baseline	**Post-Baseline**	**P-value**
MHC-SF (SD)	40.25 (14.72)	46.42 (10.83)	0.01*
Emotional Wellbeing	9.83 (3.19)	10.25 (2.49)	0.28
Social Wellbeing	11.17 (6.25)	14.50 (4.52)	0.01*
Psychological Wellbeing	19.25 (6.97)	21.67 (4.58)	0.09
Flourishing (%)	4 (33.33)	5 (41.67)	0.02*
Moderately Mentally Healthy (%)	6 (50.00)	7 (58.33)	
Languishing (%)	2 (16.67)	0 (0.00)	
AAQ-II (SD)	20.25 (9.20)	22.17 (5.83)	0.31
EACQ (SD)	37.08 (10.60)	36.33 (7.96)	0.69
CBS (SD)	40.42 (22.13)	42.33 (16.67)	0.67

** Indicates significance of $p<0.05$*

Table 5 summarises reliable change scores for participants that completed the intervention and provided outcome measure data. Participant 4 demonstrated clinically significant and reliable change in wellbeing from baseline to follow-up on the MHC-SF. Two participants (6 and 10) demonstrated transitions from above to below clinical cut-off for psychological flexibility but this did not meet RCI threshold. Another participant appeared to show reliable reverse clinically significant change in terms of reduced psychological flexibility (participant 5); moving into the 'clinically relevant distress' range post-baseline. Participant 4 also moved from severe burden to moderate burden without reliability. the EACQ was not included in this analysis as no clinical cut-off scores were available.

Table 5. Reliable Change Index Scores of Outcome Measures

PT ID				1			2			3			4		
Measure	**Rel**	**Mean**	**SD**	**Pre**	**Post**	**RCI**	**Pre**	**Post**	**RCI**	**Pre**	**Post**	**RCI**	**Pre**	**Post**	**RCI**
MHC-SF	0.89	40.25	14.72	19	29	-1.45	56	64	-1.16	41	46	-0.72	18	35	**-2.46***
AAQ-II	0.84	20.25	9.20	37	33	0.77	12	16	-0.77	10	19	-1.73	28	27	0.19
CBS	0.89	40.42	22.13	78	69	0.87	37	37	0.00	47	53	-0.58	68	57	1.06
PT ID				**5**			**6**			**7**			**8**		
Measure	**Rel**	**Mean**	**SD**	**Pre**	**Post**	**RCI**	**Pre**	**Post**	**RCI**	**Pre**	**Post**	**RCI**	**Pre**	**Post**	**RCI**
MHC-SF	0.89	40.25	14.72	34	34	0.00	35	44	-1.30	36	47	-1.59	64	58	0.87
AAQ-II	0.84	20.25	9.20	13	24	-2.11*	27	19	1.54	18	20	-0.38	11	21	-1.92
CBS	0.89	40.42	22.13	24	34	-0.96	47	58	-1.06	45	50	-0.48	8	30	-2.12
PT ID				**9**			**10**			**11**			**12**		
Measure	**Rel**	**Mean**	**SD**	**Pre**	**Post**	**RCI**	**Pre**	**Post**	**RCI**	**Pre**	**Post**	**RCI**	**Pre**	**Post**	**RCI**
MHC-SF	0.89	40.25	14.72	42	48	-0.87	39	46	-1.01	63	62	0.14	36	44	-1.16
AAQ-II	0.84	20.25	9.20	19	22	-0.58	27	23	0.77	11	12	-0.19	30	30	0.00
CBS	0.89	40.42	22.13	57	47	0.96	20	19	0.10	8	18	-0.96	46	48	-0.19

** Indicates clinical significance - a reliable clinical change (>1.96 or <-1.96) and transition from clinical to non-clinical score.*

Features of Participants Who Dropped Out

No significant differences in terms of demographic or psychological profile were observed at baseline between those participants who completed the intervention and those that dropped out. See tables 6 and 7 for further detail.

Table 6 Demographic comparison between completers and non-completers.

	Completers (n = 13)	**Non-Completers (n = 5)**	**P-value**
Mean Age (Years (SD)	68.54 (7.23)	61.00 (7.00)	0.15
Gender (Female) (%)	8 (61.54)	4 (80.00)	0.62
Employment (%)			
Retired	10 (76.92)	1 (20.00)	Does not meet assumptions
Employed	3 (23.08)	1 (20.00)	
Unemployed	0 (0.00)	2 (40.00)	
Unknown	0 (0.00)	1 (20.00)	
Relationship (%)			
Spouse/Partner	9 (69.23)	3 (60.00)	1
Child	4 (30.77)	2 (40.00)	
Duration of Caring (Months)	34.31 (SD = 23.09)	30.00 (SD = 10.39)	1
Time Caring (Days per week) (%)			
<1	1 (7.69)	0 (0.00)	Does not meet assumptions
1-3	0 (0.00)	1 (20.00)	
4-6	1 (7.69)	0 (0.00)	
Most (some breaks)	7 (53.85)	1 (20.00)	
All (no breaks)	3 (23.08)	0 (0.00)	
Unknown	1 (7.69)	3 (60.00)	
Other caring duties (%)	2 (15.38)	1 (20.00)	Does not meet assumptions

Table 7. Baseline Mean Scores for Completers/Non-Completers

	Completers (n = 13)	**Non-Completers (n = 5)**	**P-value**
MHC-SF (SD)	40.25 (14.72)	38.25 (20.02)	0.77
Emotional Wellbeing	9.83 (3.19)	7.50 (5.45)	0.52
Social Wellbeing	11.17 (6.25)	13.00 (6.33)	0.60
Psychological Wellbeing	19.25 (6.97)	17.75 (9.00)	0.86
Flourishing (%)	4 (30.77)	1 (20.00)	Does not meet assumptions
Moderately Mentally Healthy (%)	6 (46.15)	2 (40.00)	
Languishing (%)	2 (15.38)	1 (20.00)	
AAQ-II (SD)	20.25 (9.20)	32.00 (12.57)	0.13
EACQ	37.08 (10.60)	36.50 (9.95)	0.95
CBS	40.42 (22.13)	49.75 (21.11)	0.52

Qualitative Results

A total of fifteen themes emerged from the data across eight sub-categories and four broad over-arching categories. Key themes and supporting quotations are detailed below followed by presentation in summary format in table 8.

Category 1: Experience of Caring

Participants appeared to value time with other carers and spent significant periods both within the focus group and within the break spontaneously sharing experiences and ideas regarding caring. The quality of these discussions together with comments about the usefulness of the group provided insight into the need of carers to have opportunities to relate to others' experience of caring for a family member with dementia.

1.1 Challenges of Caring

Coping

Participants described the process of dementia diagnosis, changes in their relative's functioning, and their own strategies for coping with stress and adjustment *("It was a bit of a shock because I'd been looking forward to retiring and doing everything together, going on holidays and all that… I was angry within myself because I felt that all my plans had gone and I wasn't thinking of (relative)", Participant 2).*

Wider Context

Participants discussed resources available to CPwD and an awareness of the intervention within a wider context *("…there's a finite amount of money… that'll pay for a carer to go into your house or pay for us to say in a year's time to get another two and a half hours just as a reminder about this… so we can't make a judgement really except the judgement that we enjoyed it and we thought it was very helpful.", Participant 4)* and expressed their wish that the intervention would become available to other carers *("I think people would benefit from this being rolled out..." "I'd be quite sad. I think I would be quite disappointed if it wasn't available.", Participant 5; "…there's an awful lot of people going to come behind us with the same thoughts that I had... I think it's important the people behind us get it as well.", Participant 2).*

Category 2: Prospective Acceptability

2.1 Recruitment

Motivations

Prior to attending the group, participants were curious and open to a new experience *("…it was new and I wasn't sure what was expected… I wanted to come just to see what other people were dealing with and coping with.", Participant 2).* Participants were also ambivalent about potential intervention efficacy (*"I was open to anything that was going to be put forward… I came with an open mind but my expectations weren't terribly great…", Participant 3).* Some reported feeling a sense of duty to attend ("I felt kinda 'what if nobody goes, that'll be terrible, so I'll just go'", Participant 6).

Barriers

There was a range of responses in terms of issues that participants overcame to attend the group; including caring duties (*"The problem I had was…my (relative with dementia) is not to be left alone… because she wanders… she went out with some staff here to the local shops or wherever and went for a coffee.", Participant 2)* and questioning their suitability for the group *("I felt a bit I shouldn't really be here, this is really for somebody that needs it more than me…", Participant 6)*

2.2 Randomisation

Acceptance

Participants suggested that they would theoretically be willing to participate in a randomised study in the future.(*"I would accept that's part of the whole research process", Participant 1)* and partly this was assisted by the option of having another intervention made available (*"You would have had something going on to make it feel as if you were getting something, you wouldn't have just been sitting there.", Participant 5).*

Uncertainty

Whilst other participants raised concerns about the potential for future studies using an RCT design (*"I think I'd feel cheated a wee bit" … "I may be persuaded …", Participant 4).*

2.3 Evaluation Process

Clarity

Participants reported problems with the EACQ, describing it as unclear (*"The wording was difficult and I didn't know how to respond to it… you're worried that you have to answer the same question again but you can't remember how you thought about the question the first time you read it.", Participant 6*) and their concern for this appeared to demonstrate their investment in the project (*"There were a couple of questions I read and I thought 'I'm not sure what that's asking you' and I put an answer down and I thought I wanted a positive answer in there and that looks negative to me.", Participant 2).* This was a measure originally developed in Spanish and not validated with English-speaking populations.

Category 3: Concurrent Acceptability

3.1 Content

Engaging

Participants described experiencing the overall intervention as interesting, enjoyable, (*"It was like a patchwork quilt… there was something of interest in every bit…you could have it to look at or you could have it over your body but it just brought quality to your life.", Participant 1),* relevant and providing insight into their own situation *("…it's given me a bit of insight and I feel probably ammunition to cope a bit better when things do get worse.", Participant 5).*

Specifically, participants discussed the benefits of both mindfulness exercises (*"...after half an hour it was like a light bulb moment for me... and I thought 'it's as easy as that!' So I have put it into practice quite a lot to be honest." Participant 3*) and values-based activities (*"I enjoyed that bit of it, I enjoyed it because no-one's ever asked me my values.", Participant 4).*

Hopeful

There was a suggestion that the group had provided a sense of hopefulness for participants, inspiring confidence (*"We will help to share this information with the communities we love…that there is a way to get through, even when it gets to a point, a breaking point, there is a way.", Participant 1; "There is hope!", Participant 6)* and optimism (*"…enlightening, that's how I felt. I would go out...And you would think 'You know what life's not that bad after all'.", Participant 3).*

3.2 Delivery

Pacing

Participants described pacing of the group as generally acceptable and highlighted tasks that would benefit from more time (*"It was quite relaxed, there were a couple of times where we felt like we were asked (about values) … and I felt we never really had a lot of time to do that bit.", Participant 6*). Values-based exercises particularly felt rushed and participants described wanting more time to think about this new concept *("I mean nobody's ever asked me to do anything like that… so that bit was a bit rushed.", Participant 4).* Participants also commented on the intervention design of two sessions followed by a gap of two weeks before attending the last session. Respondents suggested that the longer time between sessions was not helpful in terms of consistency (*"I felt that if there'd been three weeks in a row there'd be more continuity actually.", Participant 5*) and supporting learning (*"…when you're introduced to a new concept I think having a regular input sort of reinforces it… although I just accepted it at the time..." (Participant 1*).

Space

A lack of surface space to put items on (documents, values cards, and drinks) was highlighted as problematic (*"There was no worktop to work on. Practically, that was just a stressor.", Participant 1).* Participants noted that the Values Card Sort task was quite difficult to participate in without a table and alternative solutions to this problem were suggested: *("…maybe a wee bit less (values cards)", Participant 5).*

3.3 Group Processes

Reassurance

Participants' responses suggested that the group was an open and non-judging space that provided opportunities for normalisation, validation, and mutual support to occur: (*"You could discuss your feelings openly without feeling you were an awful person… and you could empathise I think with other people as a group as well.", Participant 5: "… when I listened to the stories I found it very helpful, helped me realise I wasn't the bad one.", Participant 2; "…and reassurance, I think that was the main thing as well, knowing that you're not alone… you're not the only one that has problems. Everybody's problems are different and it's how we handle them.", Participant 3; "And you're not on your own really.", Participant 6).*

Category 4: Impact of Group

4.1 Personal Outcomes

Awareness

Present moment awareness of how participants relate to themselves and their environment was described as a beneficial outcome of attending the group: *("…it's also invited me to think in awareness and I think I've actually got some better experiences because of that. It's sharpened my actual experience, my pleasures or just my thoughts, so it's kind of wakened me up again.", Participant 1; "…it's made me more open to that and more aware of everything, so I've just found it so beneficial", Participant 3).*

Acceptance

In addition to increased awareness, participants also reported relating to themselves and care recipient from a more accepting position; *"…(the training) was illuminating as to how I was actually… talking away in my head and realising that this wasn't under my control and it's been very useful.", Participant 1; "Well I just accept some of the things, I accept some of the things that my mother says even when I know they're wrong, I'll just go 'oh right, right'. Just cause it's not worth getting wound up about.", Participant 6; "…without the ACT therapy I think that I would have struggled to cope big time and I'm starting to calm down a bit and I'm now doing what I should be doing, looking after (relative with dementia) properly. You see the not arguing with her should help her hopefully.", Participant 2).*

Self-Care

Participants enthusiastically described engaging in values-consistent actions after attending the group and finding solutions for making time to do something for themselves, such as shaping society (*"I'm kinda politically motivated trade union wise, and I'd cut that off, I'd stopped that but I thought to myself since sort of doing this sort of course 'well why don't you do something?', joined the community council", Participant 4)*, and enjoying leisure time (*"I've actually joined the (local) choir. I used to, I mean I used to sing oh over fifty years ago a lot and I thought my breathing will not be right, this'll not be right, but oh my lord it's wonderful.", Participant 3, line 1510-2, p.49).*

Table 8. Framework Developed from Focus Group Responses

Category	Sub-Category	Theme
1. Experience of Caring	1.1 Challenges of caring	Coping Wider Context
2. Prospective Acceptability	2.1 Recruitment	Motivations Barriers
	2.2 Randomisation	Acceptance Uncertainty
	2.3 Evaluation Process	Clarity
3. Concurrent Acceptability	3.1 Content	Engaging Hopeful
	3.2 Delivery	Pacing Space
	3.3 Group Processes	Reassurance
4. Impact of Group	4.1 Personal Outcomes	Awareness Acceptance Self-Care

DISCUSSION

Research into effective wellbeing interventions for CPwD is limited and there have been no known prior feasibility studies investigating an ACT group for this population. Overall, the results provide encouraging indications of feasibility in terms of recruitment of the target population, intervention fidelity and acceptability, and early signals of treatment efficacy.

Population

Feasibility results suggest that this intervention approach may be appropriate and beneficial for a variety of CPwD; including partners and adult children caring for people with different dementia diagnoses and stages of progression. The characteristics of the sample in this study were diverse in terms of age, duration of caring role, and employment status. This indicates the potential reach of the intervention and also suggests a need for further research into specific aspects regarding what type of carer might receive greatest benefit.

A sufficient number of participants were recruited to allow for the delivery of both ACT groups. Recruitment challenges were observed at one site and highlighted possible considerations for future research; including allowing suitable time for approaching and recruiting participants, identifying barriers to attendance (poor physical health, competing personal commitments), and the impact of a smaller group (increased discussion time versus reduced peer learning interactions).

Levels of carer wellbeing at baseline were variable and participants reported broad ranging levels of flourishing, psychological flexibility and burden; this echoes suggestions in the literature that experiences of being a carer of someone with dementia is as heterogeneous as the population. Significant associations were identified between baseline wellbeing, psychological flexibility and burden.

Intervention

The ACT group was assessed as adhering to the theoretical model. and results suggested that participants experienced the intervention as acceptable. Overall attrition was lower than the benchmark of 33% (Lambert & Ogles, 2004) and similar to the rate reported previously for individual ACT (Losada *et al.*, 2015). It is important, however, to consider the reasons for participant disengagement (i.e. health concerns and caring responsibilities) to provide context and further understanding of barriers to accessing support for this population. Feedback from participants who completed the group supported their overall reported intervention satisfaction. Participants described the group process as beneficial due to shared experiences and subsequent connectedness; this perhaps highlights a need for CPwD to feel more socially connected and reduce a sense of isolation as described previously (Sörensen *et al.*, 2006).

Outcomes

This feasibility study did not intend to measure clinical effectiveness of the ACT group intervention. However, efforts were made to gather evidence from both outcome measures and focus group data that provided signals of treatment benefit. Outcome measure results suggest limited effects of this brief intervention over the period that changes were measured. Some shifts towards increased overall wellbeing were observed and were most apparent within the social wellbeing domain. There were also some indications that participants made positive changes in terms of value-based behaviours which they reported as wellbeing-enhancing;

therefore, it may be useful to use a measure of value-consistent behaviour in future. No clinically significant positive changes were observed on measures of psychological flexibility or burden, as were reported by previous studies (Márquez-González, Romero-Moreno & Losada, 2010; Losada *et al.*, 2015). This may indicate that wellbeing effects are not mediated by psychological flexibility in this population or that participants, who were non-treatment seeking, demonstrated ceiling effects. Additionally, the MHC-SF appeared to be a useful tool for detecting treatment signals whereas the ambiguity of the translated EACQ limited the reliability of psychological flexibility scores. Missing items on outcome measures (MHC-SF, EACQ) also provide feasibility information for future study design.

Limitations

Due to the study design, which did not involve independent assessors completing measures with participants, it is possible that the results obtained from outcome measures and acceptability questionnaires may be have been over-estimated by bias introduced via social desirability. Future studies might overcome this potential effect by using an independent researcher to conduct measures of intervention acceptability and efficacy. The focus group data on treatment acceptability is less likely to have been biased as this was conducted by an independent facilitator.

This study did not attempt to measure longer term follow-up of carer outcomes following ACT group attendance and may have been a useful aspect to explore prior to a larger controlled study. There may also be potential limitations to the intervention design itself that could be tested in future studies (i.e. increasing the length of intervention, and duration and spacing of sessions).

Recommendations

There remains an imbalance between significant population need and a lack of effective and scalable treatment packages to support this. Feasibility and pilot studies evaluating interventions are most useful when a series of refinements are conducted and tested (Medical Research Council, 2008). It would therefore be of benefit for future evaluations of ACT groups for CPwD to consider using a similar approach prior to commencing larger scale evaluations. The possibility that this intervention can prevent CPwD from developing significant mental health problems, or might prevent exacerbation of pre-existing mental health problems, requires further investigation. Consideration of improving intervention design may also be indicated as expressed by participants and supported by approaches to working with older adults. Similarly, the number of outcome measures used and their clarity is something for researchers to be mindful of for future study iterations. Further investigations into the mechanisms of impact of the intervention would enhance understanding of carer wellbeing and ACT efficacy.

Conclusion

In summary, the ACT group appears to hold general acceptable for CPwD. Feasibility of developing this type of intervention in a healthcare setting has also been demonstrated. There are potential suggestions within these preliminary findings that wellbeing may be a useful construct to measure ACT efficacy. However, further feasibility assessments are necessary prior to a potential future full-scale evaluation of an ACT group intervention for this population.

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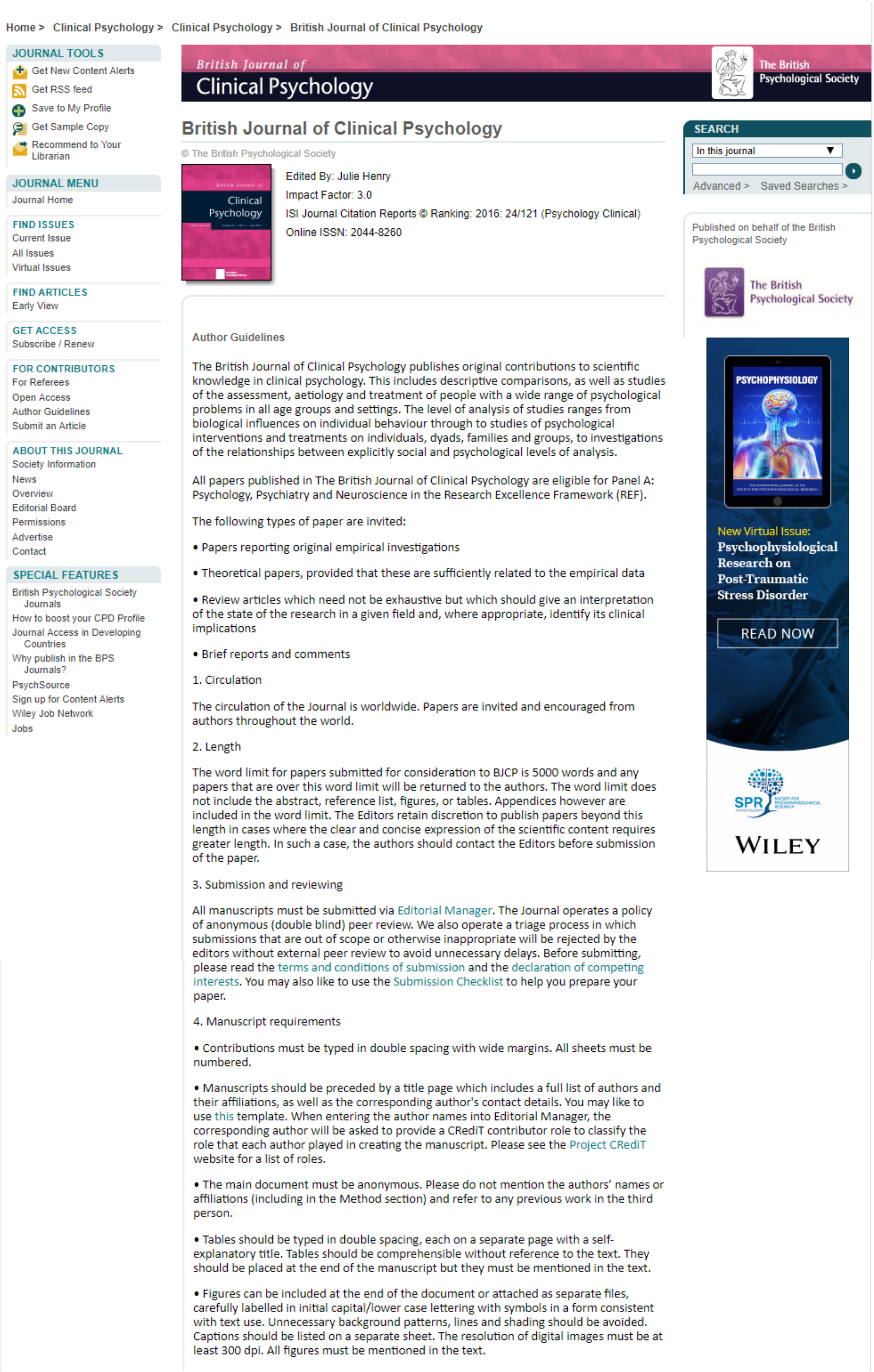
Appendix 1.1 Appendix 1.1 Submission Guidelines for the British Journal of Clinical Psychology



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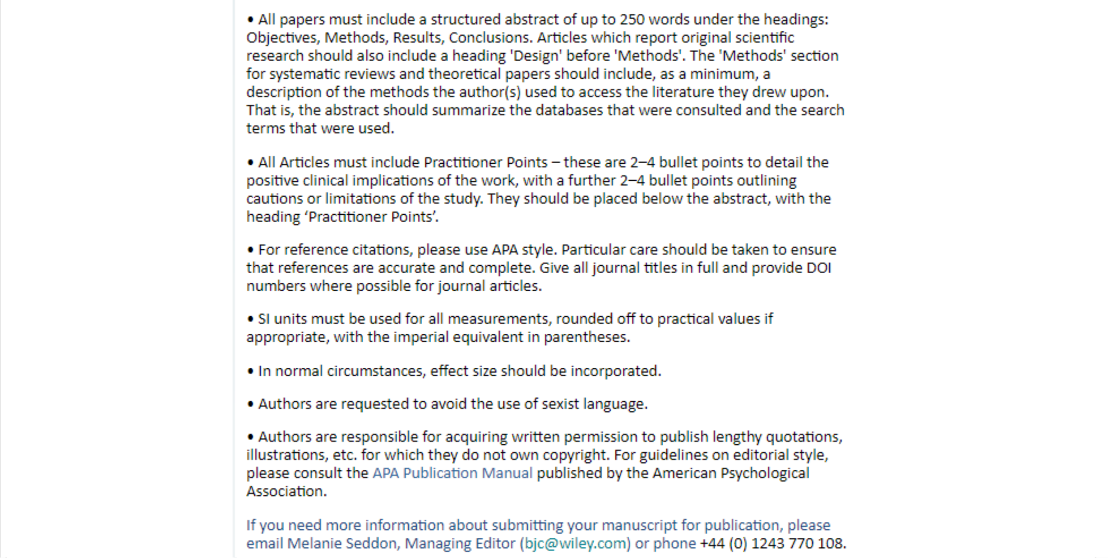

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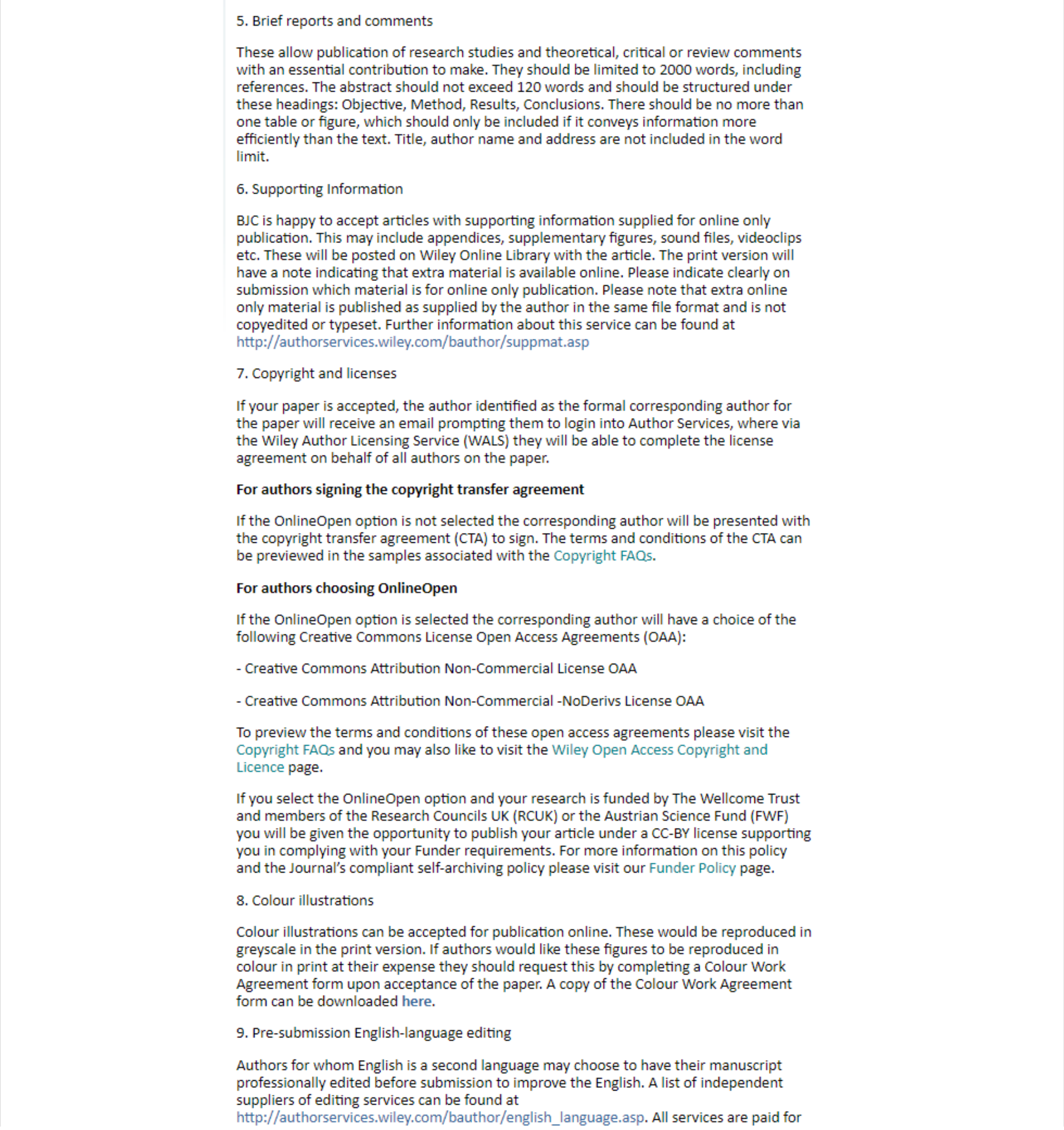

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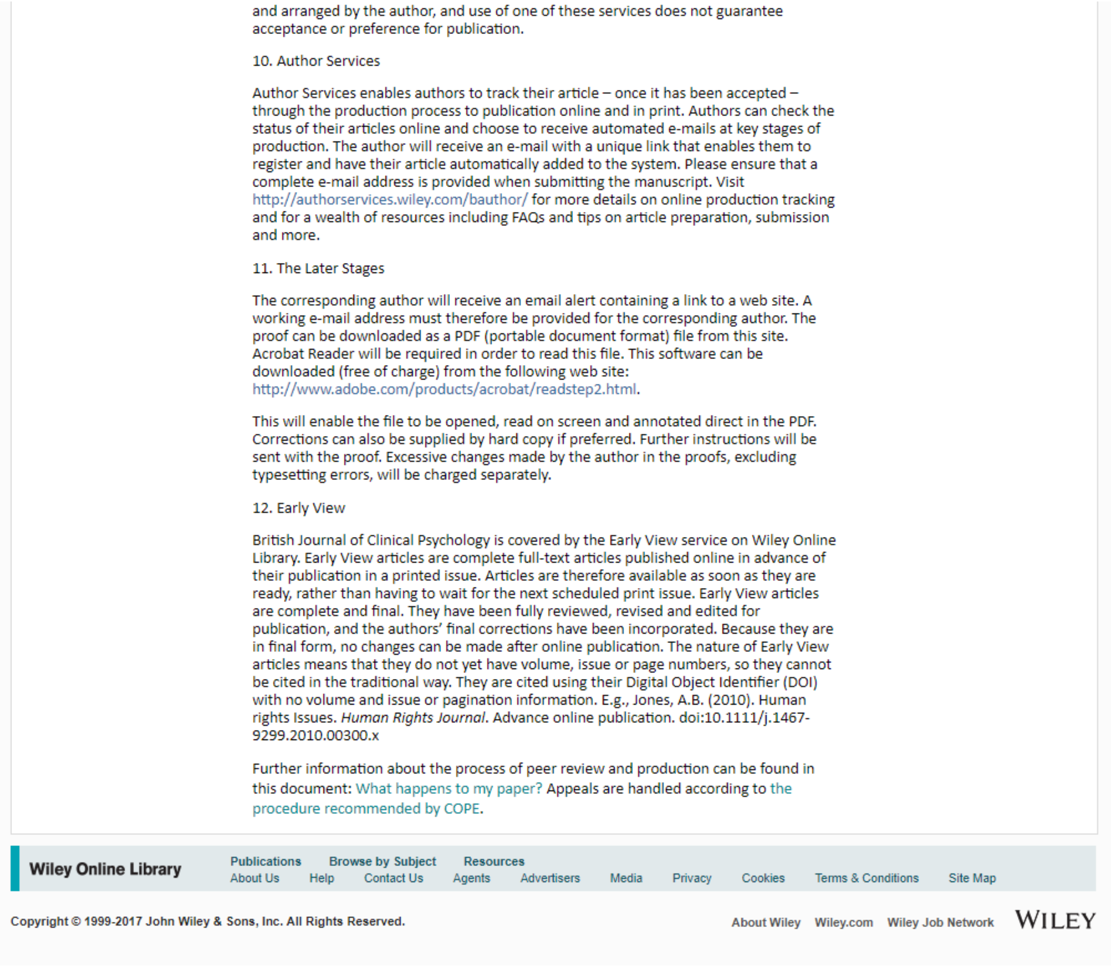

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Appendix 1.2 Search Strategy for Systematic Review

PsychInfo, CINAHL and ASSIA:

1. (carer* or care giver* or caregiver* or ((family or spous* or husband* or wife or wive* or partner*) N2 car*)
2. (dement* or alzheimer*)
3. (psychotherapy* or cognitive behavio* therapy or CBT or cognitive therapy or behavio* therapy or family therapy or systemic therapy or psychological or psychosocial or acceptance and commitment therapy or ACT or acceptance and commitment training or mindfulness or training)
4. 1 AND 2 AND 3
5. Limit to 2012-2016, journal articles and English Language

Medline and Embase:

1. Carer/
2. (carer* or care giver* or caregiver* or ((family or spous* or husband* or wife or wive* or partner*) adj2 car*)).ti,ab,kw.
3. 1 or 2
4. exp Dementia/
5. (dement* or alzheimer*).ti,ab,kw.
6. 4 or 5
7. 3 and 6
8. psychotherapy/ or behavior therapy/ or cognitive therapy/ or "acceptance and commitment therapy"/ or mindfulness/ or person-centered therapy/ or psychotherapy, brief/ or psychotherapy, multiple/ or exp psychotherapy, group/
9. 7 and 8
10. Limit 9 to English language

Appendix 1.3 Cochrane Risk of Bias Assessment Tool

RANDOM SEQUENCE GENERATION **Selection bias (biased allocation to interventions) due to inadequate generation of a randomised sequence.**	
Criteria for a judgement of 'Low risk' of bias.	The investigators describe a random component in the sequence generation process such as: • Referring to a random number table; • Using a computer random number generator; • Coin tossing; • Shuffling cards or envelopes; • Throwing dice; • Drawing of lots; • Minimization*. *Minimization may be implemented without a random element, and this is considered to be equivalent to being random.
Criteria for the judgement of 'High risk' of bias.	The investigators describe a non-random component in the sequence generation process. Usually, the description would involve some systematic, non-random approach, for example: • Sequence generated by odd or even date of birth; • Sequence generated by some rule based on date (or day) of admission; • Sequence generated by some rule based on hospital or clinic record number. Other non-random approaches happen much less frequently than the systematic approaches mentioned above and tend to be obvious. They usually involve judgement or some method of non-random categorization of participants, for example: • Allocation by judgement of the clinician; • Allocation by preference of the participant; • Allocation based on the results of a laboratory test or a series of tests; • Allocation by availability of the intervention.
Criteria for the judgement of 'Unclear risk' of bias.	Insufficient information about the sequence generation process to permit judgement of 'Low risk' or 'High risk'.

ALLOCATION CONCEALMENT

Selection bias (biased allocation to interventions) due to inadequate concealment of allocations prior to assignment.

Criteria for a judgement of ‘Low risk’ of bias.	Participants and investigators enrolling participants could not foresee assignment because one of the following, or an equivalent method, was used to conceal allocation: • Central allocation (including telephone, web-based and pharmacy-controlled randomization); • Sequentially numbered drug containers of identical appearance; • Sequentially numbered, opaque, sealed envelopes.
Criteria for the judgement of ‘High risk’ of bias.	Participants or investigators enrolling participants could possibly foresee assignments and thus introduce selection bias, such as allocation based on: • Using an open random allocation schedule (e.g. a list of random numbers); • Assignment envelopes were used without appropriate safeguards (e.g. if envelopes were unsealed or nonopaque or not sequentially numbered); • Alternation or rotation; • Date of birth; • Case record number; • Any other explicitly unconcealed procedure.
Criteria for the judgement of ‘Unclear risk’ of bias.	Insufficient information to permit judgement of ‘Low risk’ or ‘High risk’. This is usually the case if the method of concealment is not described or not described in sufficient detail to allow a definite judgement – for example if the use of assignment envelopes is described, but it remains unclear whether envelopes were sequentially numbered, opaque and sealed.

BLINDING OF PARTICIPANTS AND PERSONNEL

Performance bias due to knowledge of the allocated interventions by participants and personnel during the study.

Criteria for a judgement of ‘Low risk’ of bias.	Any one of the following: • No blinding or incomplete blinding, but the review authors judge that the outcome is not likely to be influenced by lack of blinding; • Blinding of participants and key study personnel ensured, and unlikely that the blinding could have been broken.
Criteria for the judgement of ‘High risk’ of bias.	Any one of the following: • No blinding or incomplete blinding, and the outcome is likely to be influenced by lack of blinding; • Blinding of key study participants and personnel attempted, but likely that the blinding could have been broken, and the outcome is likely to be influenced by lack of blinding.
Criteria for the judgement of ‘Unclear risk’ of bias.	Any one of the following: • Insufficient information to permit judgement of ‘Low risk’ or ‘High risk’; • The study did not address this outcome.

BLINDING OF OUTCOME ASSESSMENT

Detection bias due to knowledge of the allocated interventions by outcome assessors.

Criteria for a judgement of 'Low risk' of bias.	Any one of the following: • No blinding of outcome assessment, but the review authors judge that the outcome measurement is not likely to be influenced by lack of blinding; • Blinding of outcome assessment ensured, and unlikely that the blinding could have been broken.
Criteria for the judgement of 'High risk' of bias.	Any one of the following: • No blinding of outcome assessment, and the outcome measurement is likely to be influenced by lack of blinding; • Blinding of outcome assessment, but likely that the blinding could have been broken, and the outcome measurement is likely to be influenced by lack of blinding.
Criteria for the judgement of 'Unclear risk' of bias.	Any one of the following: • Insufficient information to permit judgement of 'Low risk' or 'High risk'; • The study did not address this outcome.

INCOMPLETE OUTCOME DATA

Attrition bias due to amount, nature or handling of incomplete outcome data.

Criteria for a judgement of 'Low risk' of bias.	Any one of the following: • No missing outcome data; • Reasons for missing outcome data unlikely to be related to true outcome (for survival data, censoring unlikely to be introducing bias); • Missing outcome data balanced in numbers across intervention groups, with similar reasons for missing data across groups; • For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk not enough to have a clinically relevant impact on the intervention effect estimate; • For continuous outcome data, plausible effect size (difference in means or standardized difference in means) among missing outcomes not enough to have a clinically relevant impact on observed effect size; • Missing data have been imputed using appropriate methods.
Criteria for the judgement of 'High risk' of bias.	Any one of the following: • Reason for missing outcome data likely to be related to true outcome, with either imbalance in numbers or reasons for missing data across intervention groups; • For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk enough to induce clinically relevant bias in intervention effect estimate; • For continuous outcome data, plausible effect size (difference in means or standardized difference in means) among missing outcomes enough to induce clinically relevant bias in observed effect size;

	• ‘As-treated’ analysis done with substantial departure of the intervention received from that assigned at randomization; • Potentially inappropriate application of simple imputation.
Criteria for the judgement of ‘Unclear risk’ of bias.	Any one of the following: • Insufficient reporting of attrition/exclusions to permit judgement of ‘Low risk’ or ‘High risk’ (e.g. number randomized not stated, no reasons for missing data provided); • The study did not address this outcome.
SELECTIVE REPORTING **Reporting bias due to selective outcome reporting.**	
Criteria for a judgement of ‘Low risk’ of bias.	Any of the following: • The study protocol is available and all of the study’s pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way; • The study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified (convincing text of this nature may be uncommon).
Criteria for the judgement of ‘High risk’ of bias.	Any one of the following: • Not all of the study’s pre-specified primary outcomes have been reported; • One or more primary outcomes is reported using measurements, analysis methods or subsets of the data (e.g. subscales) that were not pre-specified; • One or more reported primary outcomes were not pre-specified (unless clear justification for their reporting is provided, such as an unexpected adverse effect); • One or more outcomes of interest in the review are reported incompletely so that they cannot be entered in a meta-analysis; • The study report fails to include results for a key outcome that would be expected to have been reported for such a study.
Criteria for the judgement of ‘Unclear risk’ of bias.	Insufficient information to permit judgement of ‘Low risk’ or ‘High risk’. It is likely that the majority of studies will fall into this category.

OTHER BIAS **Bias due to problems not covered elsewhere in the table.**	
Criteria for a judgement of ‘Low risk’ of bias.	The study appears to be free of other sources of bias.
Criteria for the judgement of ‘High risk’ of bias.	There is at least one important risk of bias. For example, the study: • Had a potential source of bias related to the specific study design used; or • Has been claimed to have been fraudulent; or • Had some other problem.
Criteria for the judgement of ‘Unclear risk’ of bias.	There may be a risk of bias, but there is either: • Insufficient information to assess whether an important risk of bias exists; or • Insufficient rationale or evidence that an identified problem will introduce bias.

Appendix 1.4 Risk of Bias Data Table

Study	Random sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment	Incomplete outcome data	Selective reporting	Other bias
Au (2015)	Unclear No information reported about randomisation process or sequence generation.	Low *“Research staff carrying out the assessments and interventions had no knowledge of the allocation”*	Low *“Research staff carrying out the assessments and interventions had no knowledge of the allocation”*	Low No knowledge of allocation and *“All assessments… were carried out by research staff not involved in (delivering any) interventions”*	Low Missing data balanced across intervention groups and due to reasons unlikely to be related to true outcome *(“care recipients were admitted to hospital”*).	Unclear No information about study protocol or published reports	Low No additional bias identified
Chen et al. (2015)	Low *“Block randomization with equal sizes was used as the method of randomization… using a computerized random number generator”*	Low *“The allocation schedule was created by an independent researcher”*	Unclear The study did not address this outcome	Low *“the allocation schedule was created by an independent researcher, who was unknown to the investigators of this study”*	Unclear Eleven individuals did not complete the study after enrolment; no information as to how missing data were managed or reasons for dropout.	Unclear No information about study protocol or published reports	Low No additional bias identified

Study	Random sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment	Incomplete outcome data	Selective reporting	Other bias
Cristancho-Lacroix et al. (2015)	Low *"Participants were recruited and randomized offline in 2 parallel groups based on a computer-generated randomization list using blocking and stratification by sex and relationship (spouses vs non-spouses)"*	Unclear No information regarding the method of concealment.	Low *"This study aimed to evaluate through a pilot un-blinded randomized controlled trial the efficacy and acceptability of a Web-based psychoeducational program for informal caregivers of persons with Alzheimer's disease (PWAD) based on a mixed methods research design".* However, this is unlikely to have impacted on the outcome of the study.	High Non-blinded face-to-face outcome assessments	Low *"missing data within each scale were treated according to the recommendations of the literature when available. Otherwise, simple mean imputation was used. The last observation carried forward method was used for participants who dropped out". "All available data at baseline were analyzed by intention-to-treat analysis"* and similar rate of dropout and numbers analysed	Low Protocol is available *"the in-depth description of the protocol study has been reported elsewhere"* (Cristancho-Lacroix et al., 2013). The results reflect the hypotheses outlined in the paper.	Low No additional bias identified

Study	Random sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment	Incomplete outcome data	Selective reporting	Other bias
Gonyea, López & Velásquez (2016)	Low *“through block randomization, caregivers were assigned to one of two study arms”.*	Unclear No information regarding the method of concealment.	Unclear No information regarding blinding of participants.	Unclear No information regarding blinding of assessors.	Low Appropriate imputation of missing data and ITT analysis carried out: *“limited participant attrition occurred at post-test (three cases) and follow-up (six cases)… missing data on the core outcome measures… were estimated using the multiple imputation procedure… repeated analyses without imputation for missing post-tests to compare against (ITT)”*	Unclear No information about study protocol or published reports	Low No additional bias identified

Study	Random sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment	Incomplete outcome data	Selective reporting	Other bias
Kajiyama et al. (2013)	Unclear No information reported about randomisation process or sequence generation.	Unclear No information regarding the method of concealment.	Unclear No information regarding blinding of participants.	Unclear No information regarding blinding of assessors.	High Significant dropout (31.3%) of participants. Numbers were relatively balanced across the two groups, when accounting for recipient deaths. Unclear how dropout has been accounted for in the analysis. Participants were *"excluded because of significant missing data".* Unclear how missing data has been dealt with that is not *"significant"*.	Low Previous results reported: *"Based on our past results with the CWC protocol we designated a measure of perceived stress as the primary outcome reported in ClinicalTrials.gov "*	Low No additional bias identified

Study	Random sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment	Incomplete outcome data	Selective reporting	Other bias
Kamkhagi et al. (2015)	Unclear No information reported about randomisation process or sequence generation.	Unclear No information regarding the method of concealment.	Low *“Single blinded”* design - participants were not aware of condition allocation.	Unclear No information regarding blinding of assessors.	Unclear No reference to missing data, or indication of attrition rates.	Unclear No information about study protocol or published reports	Low No additional bias identified
Livingston et al. (2013)	Low *“To conceal allocation we used an online computer generated randomisation system to allocate participants to the intervention or to treatment as usual”. “Randomisation was stratified by trust using random permuted blocks”.*	Low *“This system was set up and maintained by an independent clinical trials unit and accessed by the START trial manager”.*	Low Neither participants nor therapist personnel were blinded to the group of participants; however, the outcome is unlikely to be influenced by this.	Low *“… blinded outcome assessors to randomisation status”. “Assessors asked participants at the beginning of each interview not to disclose their allocation group”.*	Low *“…carried out all analyses by (ITT) but excluded carers with data missing at both the four and the eight month follow-up”. “Using logistic regression”* and *“repeated the main analyses adjusting for those factors associated with missingness”.*	Low Study protocol available and referenced: ”the supplementary file provides the full protocol of this pragmatic multicentre randomised controlled trial”	Low No additional bias identified

Study	Random sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment	Incomplete outcome data	Selective reporting	Other bias
Losada et al. (2015)	Low Randomisation occurred *“using computer generated numbers”.*	Unclear No information regarding the method of concealment.	Unclear No information regarding blinding of participants.	Low *“All the assessments were done by psychologists trained in the assessment protocol, who were blind to treatment conditions and to the main hypotheses of the study”*	Unclear Although authors report *“assessed variables between completers and those who dropped out of the study… through differences between means and independence tests”,* no indication that ITT analysis was used. Similar dropout rate across groups.	Unclear No information about study protocol or published reports	Low No additional bias identified
Moore et al. (2013)	Low *“A computerized random number generator was used to randomize caregivers”.*	Unclear No information regarding the method of concealment.	Low *“Throughout the trial assessors and the research nurse were blind to randomization condition.”*	Low *“Throughout the trial assessors and the research nurse were blind to randomization condition”.*	Low ITT analysis “… included all 100 randomized participants”. Similar dropout rate across groups.	Unclear No information about how to access study protocol, although.	Low No additional bias identified

Study	Random sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment	Incomplete outcome data	Selective reporting	Other bias
Prick et al. (2015)	Low *“We made use of the block randomization method to randomize the dyads into groups that result in equal sample sizes to ensure a balance in sample size across the two groups over time, which is a method of true randomization. An independent researcher made the random allocation schedule”.*	Unclear Allocation was blind at the point of allocation however *“although at the start of each measurement, examiners were blinded to the group allocation and dyads were asked not to disclose their group allocation, in practice group allocation became clear to the examiners during the intervention period”.*	Low Not blinded: *“Self-evidently, dyads, and coaches were aware of the treatment assigned”,* however, this is unlikely to have affected outcomes.	High *“Although at the start of each measurement, examiners were blinded to the group allocation and dyads were asked not to disclose their group allocation, in practice group allocation became clear to the examiners during the intervention period’.*	Low *“At all stages of data analysis, the intention to treat (ITT) analyses were performed, including all participants as originally allocated after randomization”, “ In addition to ITT analysis, compliance analyses were performed”*	Low Protocol available in another article (Prick et al., 2011). The results reflect the hypotheses outlined in the paper.	Low No additional bias identified

Study	**Random sequence generation**	**Allocation concealment**	**Blinding of participants and personnel**	**Blinding of outcome assessment**	**Incomplete outcome data**	**Selective reporting**	**Other bias**
Tremont et al. (2015)	Low *"…using an urn randomization procedure",* which is systematically biased in favour of balance and is only appropriate for large samples (N = 250).	Unclear No information regarding the method of concealment.	Unclear No information regarding blinding of participants.	Low *"Outcome assessments were conducted face-to-face at the baseline (prior to random assignment) and by telephone at the 6-month assessment by a research assistant who was blind to group membership". "Therapists did not have access to any assessment results"*	Low *"If two consecutive contacts were missed, caregivers were considered lost to follow up and identified as dropouts". There were no significant group differences in dropout. "Logistic regression analysis was used to identify predictors of dropout".*	Low Study procedures and baseline data previously published (Tremont et al., 2013). The results reflect the hypotheses outlined in the paper.	Low No additional bias identified

Study	Random sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment	Incomplete outcome data	Selective reporting	Other bias
Waldorff et al. (2012)	Low *"The randomisation was done with Stat Direct version 2.3.7. We used a random block size algorithm to prevent imbalance between the groups".*	Low *"The allocation procedure was concealed for the (intervention) group and was conducted by an independent department"* Further information provided in previous paper *"The assignment to group was done via letters from the central office to the local study coordinators"* (Waldemar et al., 2010).	Low Participants were not blinded *"Patients and caregivers were instructed to try not to reveal which treatment arm they were in"* (Waldemar et al., 2010). Personnel were blinded *("rater blinded trial").* This is unlikely to have impacted on outcome.	Low *"The follow-up visits were home visits… by independent raters unaware of the randomization code." "The efficiency of concealment was checked using a questionnaire to the raters at the end of each follow-up visit. None of the raters visited the same patient-caregiver couple more than once."* (Waldemar et al., 2010).	Low ITT analysis; *"Differential drop out from the study may cause bias, …To adjust for such bias, the measurements that were available at 6 and 12 month follow up were weighted by the inverse of an estimate of the probability of staying in the study".* Missing data described and balanced across groups.	Low Study procedures previously published (Waldemar et al., 2010). The results reflect the hypotheses outlined in the paper.	Low No additional bias identified

Study	Random sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment	Incomplete outcome data	Selective reporting	Other bias
Whitebird et al. (2012)	Low Participants were *“randomly assigned using a computer algorithm for simple randomization”.*	Unclear No information regarding the method of concealment.	Unclear No information regarding blinding of participants.	Unclear No information regarding blinding of assessors.	Low *“We chose the mixed-model approach because… it ensured an (ITT) analysis”.*	Unclear No information about how to access study protocol however,	Low No additional bias identified
Wilz & Soellner (2016)	High Non-randomised arm: *“not designed in the trial proposal. No selection bias was assumed in the non-randomized, telephone-only group… willing to participate before they knew that they would be selected for this intervention group”.*	Unclear “*Independent data management and biometry center was involved to ensure randomization and blinded assessment”* However, one condition was not randomised.	Unclear No information regarding blinding of participants.	Low *“An independent data management and biometry center was involved to ensure randomization and blinded assessment”.*	Low *“In the case of intervention dropout (IG and PMR), efforts were made to keep participants in the trial as regards assessments. Missing values were not replaced”.* Intent to treat analysis used.	Unclear No information about study protocol or published reports	High Analysed randomised and non-randomised intervention arms together: *“Given this similarity we decided to analyze the intervention effects for both intervention groups together”.*

Appendix 2.1 Major Research Project Proposal

Course 9 Major Research Project Proposal

A feasibility study of Acceptance and Commitment Therapy to promote the wellbeing of carers of people with dementia.

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Abstract

Background

Carers of people with dementia are more likely to experience reduced wellbeing; including poor physical and mental health. There is emerging evidence to suggest that Acceptance and Commitment Therapy (ACT), is a third wave cognitive behavioural therapy has positive effects on individuals' subjective wellbeing (i.e. their levels of 'Flourishing'). To date, the potential efficacy of ACT for enhancing subjective wellbeing in carers of people with dementia has not been fully explored.

Aims

The primary aim of this study is to access the feasibility of delivering an ACT group intervention aimed at increasing levels of subjective wellbeing in carers of people with dementia. The study will measure four components relevant to the issue of feasibility (i.e. Can participants be recruited to the groups? Is the intervention acceptable to participants? Can the intervention be delivered with fidelity? Can treatment signals be detected within outcome measures?). A process evaluation framework approach will be used throughout the study to provide further information regarding processes of change.

Applications

The current study will inform clinicians and researchers if it feasible and potentially useful to deliver an ACT intervention in a group format to carers of people with dementia. It is also hoped that the findings of this feasibility study will help inform the design of further studies to assess the effectiveness of ACT interventions for carers of people with dementia.

Introduction

The proportion and number of older people in the UK is growing, and is predicted to continue to grow over the next decade (The Scottish Government, 2010). There are 850,000 people with dementia in the UK, with numbers set to rise to over 1 million by 2025 (Alzheimer's Society, 2014). There are estimated to be over 670,000 people in the UK acting as primary, unpaid carers for people with dementia; this saves an estimated £11 billion each year (Alzheimer's Society, 2014). Carers of people with dementia (CPwD) are likely to experience reduced psychological and physical wellbeing; including depression, poor self-care and raised blood pressure following burden and stress (Burns & Rabins, 2000). It has been suggested that CPwD may under-report the distress that they experience and may therefore be underestimated by professionals (Neil & Bowie, 2008).

Gallagher-Thompson and Coon (2007) conducted a systematic review of the evidence base for psychological interventions for distress in care givers of older adults from 1980 to 2005. The authors concluded that there was strong evidence for the effectiveness of three psychological intervention types for CPwD (13 psychoeducation, 2 psychotherapy (both CBT), 2 multi-component), as measured by reductions in depression and/or burden. An updated systematic review of the evidence for psychological interventions for CPwD was conducted for studies in 2005-2011, including the addition of qualitative studies (8 psychoeducation, 1 psychotherapy, 6 multi-component, 5 technology-based) (Elvish et al., 2013). Similarly, the conclusions were that evidence supports the use of psychological interventions, particularly cognitive behavioural approaches, for reducing distress in this population. Outcome measures included distress and self-efficacy as well as depression and burden; one psychoeducational intervention (Perren, Schmid, & Wettstein, 2006) also measured emotional wellbeing. Elvish et al. (2015) suggested that conducting further psychotherapy intervention studies that provide information about processes of change would help to enhance the evidence base.

Acceptance and Commitment Therapy

Acceptance and Commitment Therapy (ACT) is a 'third wave' cognitive behavioural therapy that applies mindful-acceptance, commitment and behaviour change processes to increase individuals' psychological flexibility (Hayes et al., 2006). 'Psychological flexibility' is the ability to contact the present moment in an open and accepting way and engage in behaviours that are consistent with your values. Conversely, psychological inflexibility is thought to underpin many emotional and behavioural difficulties (Hayes, Luoma, Bond, Masuda, & Lillis, 2006). ACT is distinct from other types of cognitive behavioural therapy as it does not aim to change the content of thoughts per se, instead seeking to change an individual's relationship to their thoughts so that the person can engage in value consistent behaviour.

Mental Health and Mental Illness

Recent theories have proposed that mental health and mental illness form separate continua (Westerhof & Keyes, 2010). This is consistent with WHO definitions of mental health that emphasises not merely an absence of mental illness but also the presence of mental wellbeing (WHO, 2013). This has stimulated greater research interest in what has been referred to more generally as subjective wellbeing.

The term 'flourishing' emerged from positive psychology research and has been described as a state of mental health that encapsulates an individual experience of emotional, psychological, and social wellbeing (Keyes & Haidt, 2003). In order to operationalise this construct the Mental Health Continuum (measuring emotional, psychological and social wellbeing) was developed (Keyes, 2002). Although ACT aims to increase psychological flexibility, recent research has demonstrated that ACT interventions can lead to increased levels of flourishing (Bolmeijer, Lamers & Fledderus, 2015). This highlights a need to investigate associations between 'flourishing' and psychological flexibility further and to assess the impact that ACT interventions can have on subjective wellbeing.

Recent meta-analyses of ACT studies demonstrate that, as a transdiagnostic model, ACT is effective compared with standard treatment across a wide range of clinical and non-clinical populations (Ost 2014; Powers, Zum Vörde Sive Vörding, & Emmelkamp 2009; Ruiz 2012). ACT has been demonstrated to reduce distress when delivered to carers; including spousal caregivers of people with brain injury (Williams et al. 2014), support staff of people with intellectual disabilities (Noone & Hastings, 2010), and parents of children with autism (Blackledge & Hayes, 2006). Psychological inflexibility has been shown to be positively correlated with carer distress (Losada, Márquez-González, Romero-Moreno, & Lopez, 2014).

There are few published results of ACT interventions delivered to CPwD. A non-randomised controlled trial pilot study of a group-based ACT intervention for CPwD conducted in Spain demonstrated significant increases in caregiver psychological flexibility (Márquez-González, Romero-Moreno, & Losada, 2010). A subsequent RCT, comparing individual ACT and CBT interventions for CPwD experiencing depression, also reported a significant increase in psychological flexibility and reduced anxiety symptoms unique to the individual ACT condition (Losada et al., 2015). Participants were volunteers with depression and the authors compared individualised treatment with a group design control; therefore limiting generalisability and interpretation of the treatment effects. The ACT intervention did result in significant and clinically meaningful changes in depression symptoms post-intervention but reductions were maintained in the CBT arm only. However, in terms of acceptability, core components of CBT (self-focus and change-focus) have been resisted by and/or reported as being impractical for this population i.e. carers wanted to consider the thoughts and feelings of those they cared for rather than their own, and the context they were in was often considered to be unchangeable; e.g. dementia (Losada & Márquez-González, 2011).

This project will aim to assess the feasibility of an ACT group intervention for CPwD. When evaluating a complex intervention it is important to conduct significant development and piloting work (Medical Research Council, 2008). The Population, Intervention, Control and Outcome (PICO) framework (Oxman, Sackett, & Guyatt, 1993; Richardson, Wilson, Nishikawa, & Hayward, 1995) will be adhered to ensure that this is a well-constructed feasibility study. The importance of analysing particular key processes in complex intervention studies to explore ways of maximising the generalisability of trials and establishing evidence that can inform both practice and policy has been emphasised. Therefore a *process evaluation framework* (Moore et al., 2015) will also be applied throughout the study to consider factors relating to the implementation, mechanisms of impact, and context of the intervention (see Appendix D for logic model).

Aims and hypotheses

This project aims to evaluate the feasibility of delivering an ACT intervention to promote the subjective wellbeing of CPwD. Due to the preliminary nature of this work, the study will be uncontrolled and designed with the purpose of developing an understanding of the feasibility and processes involved in running ACT groups with CPwD. The focus of the study is to investigate the following research questions:

Population:

a) What are the numbers of potential participants identified who fulfil eligibility criteria?
b) What proportion of potential participants provide fully informed consent to participate in the study?
c) What are participants' baseline levels of psychological flexibility, flourishing, and carer burden?

Intervention:

d) Will the ACT group intervention be acceptable to CPwD?
    1. What proportion of participants are retained throughout the intervention?
    2. What feedback do participants provide regarding their experiences of the group?
e) Can the intervention be delivered with fidelity?

Outcomes:

f) What differences occur between pre- and post- measures of psychological flexibility, flourishing, and carer burden?
g) How helpful and effective do participants evaluate the group to be?
h) What are the rates of retention at follow-up?

i) Are there identifiable features of those participants that drop out of the group or are lost to follow-up?

Plan of Investigation

Design

This project will be an uncontrolled feasibility trial, using convenience sampling, and measuring a range of variables pertinent to the feasibility of delivering ACT intervention groups for CPwD. Process evaluation methodology, including quantitative and qualitative methods, will be applied to measure feasibility of the group intervention and develop a greater understanding of the intervention delivered and its causal assumptions (see research questions above) (Moore et al., 2015).

Quantitative data collected will include demographic information, number of participants recruited and retained throughout the study, outcome measures (carer burden, psychological flexibility, flourishing), and responses to Likert scale acceptability questions.

Qualitative data will include responses to open-ended acceptability questions in the format of a questionnaire and focus group exploring participants' experience of attending the groups.

Participants

Two groups of participants will receive the ACT group intervention (Total N=24; N/Group = 12). One group of participants (N=8) who attend the ACT intervention will be invited to a focus group exploring intervention acceptability.

Eligibility Criteria

Participants will consist of carers of people with a diagnosis of any type of dementia who are 18 years and over; they will have been the primary caregiver of the person with dementia for 3 months or more (as per Losada et al., 2015).

Participants will be excluded from the study if they are receiving any type of concurrent psychotherapy when consent to participate is sought.

A screening tool detailing inclusion and exclusion criteria will be developed to assist recruitment.

Recruitment

Prior to recruitment commencing the researcher will present details of the study (recruitment procedures, eligibility criteria etc.) to the relevant Community Mental Health Teams (CMHTs) and at the Older Adult Psychology Team meeting. CPwD will be identified by NHS staff working in Older People's CMHTs within GG&C. Specifically, participants will be recruited from the Woodlands OA CMHT in East Dunbartonshire and the Goldenhill OA CMHT in West Dunbartonshire.

Potential participants will provide permission for their contact details to be passed to the research team using 'Notice of Interest' slip. The researcher will then arrange to meet with the carer to recruit them to the study. Informed consent will be sought and a member of the research team will complete a consent form with participants after they have had time to read the Participant Information Sheet. Consenting participants will be sent appointment letters with further details of the group.

ACT Intervention

The ACT intervention will be delivered to 2 groups of up to 12 people per group by two clinicians trained in delivering ACT. Allowing for estimates of attrition of 33%, this will lead to 8 individuals completing both groups. All sessions will be audio recorded and assessed for fidelity to the ACT model using a measure developed by Dr Ross White in conjunction with colleagues at the University of Glasgow.

The intervention protocol is grounded in group-based work developed by Bond, Lloyd and Flaxman (Bond, 2004; Flaxman, Bond & Livheim, 2013; Lloyd, Bond & Flaxman, 2013). The protocol will be delivered using a "two-plus-one" methodology; two half day (2.5hours) group ACT sessions will be delivered one week apart followed by a third session 2 weeks following the second session.

Research Procedures

Pre- and post-measures will be completed by all participants at baseline and 21 days post-baseline. Baseline measures will be completed prior to the first session. Post-baseline measures will be completed following the third session. Feedback surveys will be given to all participants at the last group session with Likert scales and free text boxes for reflections on their experience of attending the ACT groups.

Focus groups have been suggested as the optimum method for assessing acceptability of interventions (Bowen et al., 2009). A focus group of 8 participants who have completed the ACT group intervention will be conducted by a facilitator independent from the ACT group facilitators. The participants will be selected to provide a range of experiences of the group to elicit rich discussion and qualitative data regarding acceptability (Moore et al., 2015). A semi-structured interview will be used to guide discussions (including open questions related to group format and structure, ACT approach, practicalities of attending) but the participants will be encouraged to openly discuss their opinions of their experience of the ACT group.

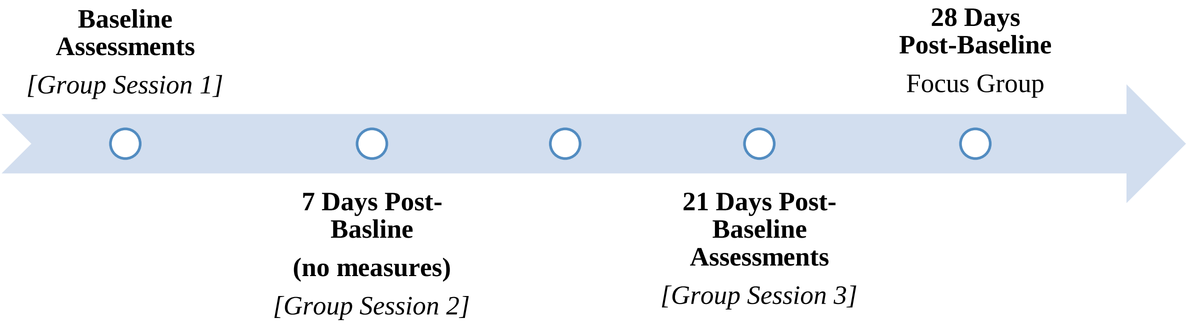

Figure 1. Timeframes for ACT groups

Measures

The following outcome measure tools will be used to assess the efficacy of the ACT intervention.

Acceptance and Action Questionnaire-II (AAQ-II; Bond et al., 2011)

The AAQ-II measures the key concept that ACT interventions aim to address, i.e. psychological inflexibility. It has been used in studies evaluating ACT interventions and possesses good psychometric properties; mean internal consistency 0.84 and 3 and 12 month test-retest reliability 0.81 and 0.79 respectively (Bond et al., 2011). The AAQ-II consists of 7 statements (e.g. 'I'm afraid of my feelings', 'Emotions cause problems in my life') that the responder rates using a 7 item Likert scale ranging from 'never true' to 'always true'.

Mental Health Continuum Short Form (MHC-SF; Keyes, 2002)

The MHC-SF measures the presence and absence of mental health i.e. levels of 'flourishing' and 'languishing' respectively. The MHC-SF consists of 14 items which measure three clusters of wellbeing (emotional, social and psychological) and has been evaluated to hold sound psychometric properties; mean internal consistency 0.89 and 3 and 9 month test-retest reliability both 0.65 (Lamers et al. 2011). Those completing the MHC-SF are asked to assess how many times they felt a certain way (e.g. 'interested in life', 'that people are basically good') during the past month and are given 6 Likert scale response choices, ranging from 'never' to 'every day'.

Experiential Avoidance in Caregiving Questionnaire (EACQ; Losada et al., 2014)

The EACQ measures EA experienced by carers. This questionnaire is quite new in its development, however, it was specifically evaluated using a sample of CPwD and has been reported to have "acceptable psychometric properties" with mean internal consistency 0.70 (Losada et al. 2014). The EACQ consists of 15 statements (e.g. 'I have never felt bad in relation to caring for my relative', 'I cannot bear it when I get angry with my relative'), which the responder is asked to rate on a 5-item Likert scale ranging from 'Not at all' to 'A lot'.

Caregiver Burden Scale (CBS; Zarit et al. 1980)

The CBS measures the overall level of burden carers experience in relation to their spouse or relative. The CBS is reported to have mean internal consistency of α=0.89 (Zarit, Antony, & Boutselis, 1987). The CBS consists of 21 items grouped into 6 subsections (e.g. The first section consists of 3 questions: ‘In general, how often do you feel: There is not enough time for yourself; Overtaxed with responsibilities; Like you’ve lost control over your life’). Responders are asked to rate each statement on a 5-item Likert scale ranging from ‘No burden at all’ to ‘Extreme burden’.

Acceptability of Intervention

Participants will be asked to complete an evaluation of their experience of the ACT group intervention. This will be a semi-structured questionnaire including boxes for free text to encourage reflection of their experience of being part of the ACT group. A smaller number of participants (n = 8) will also be invited to attend a focus group to explore their view of taking part in the ACT groups. This will be audio-recorded and transcribed for analysis.

Recruitment and Retention Parameters

A sample size of at least 12 people per group as suggested by Julious (2005) for pilot pharmaceutical studies will be an indicator of sufficient recruitment. However, 8 has been suggested as the optimum number of group participants in psychological interventions (Yalom, 1995). Therefore, a figure of no more than 33% attrition from baseline to final assessment will be used to indicate that the ACT group intervention is feasible in terms of retention (Lambert & Ogles, 2004).

Data Analysis

Population

The numbers of people referred, assessed and recruited will be provided in the form of a CONSORT flow chart. This will highlight rates of recruitment to the ACT intervention, and facilitate investigations into rates of attrition across the trial period.

Intervention

The total number of people who attended the ACT groups together with the number of non-attendances per session will be presented. Qualitative data will provide valuable information about what specifically was acceptable and not acceptable regarding the intervention by analysing Likert scale responses. Retention rates will be calculated as a further indication of acceptability. Protocol adherence and model fidelity, as measured by the fidelity assessor, will be calculated using a measure developed by staff in Mental Health and Wellbeing, University of Glasgow. Qualitative data, gleaned from open-ended question responses on acceptability questionnaires and focus group responses, will be analysed using Framework Analysis methods (Ritchie & Spencer, 1994). This method is especially useful to gain information about specific pre-conceived questions (i.e. intervention acceptability) and is a structured approach to analysing qualitative data.

Outcomes

To investigate potential treatment signals on the outcome measures, repeated-measures inferential statistics will be used. Tests of normality will determine whether parametric tests or non-parametric equivalents will be used.

Justification of Sample Size

Due to the preliminary nature of this work, effect sizes are not available to facilitate a sample size calculation to ensure that the study is sufficiently powered. However, analysis using G-Power 3 software (Faul, 2010) the following sample sizes would be needed for this study to reach statistical power values for a moderate effect size of 0.5 (assuming $\alpha = 0.05$):

Power	0.75	0.80	0.85	0.90
Sample Size	23	27	31	36

Settings and Equipment

All groups will be conducted within meeting rooms within older people’s CMHTs across GG&C. Booking of rooms will be made ahead of time to ensure the smooth running of the study. Equipment needed during the ACT group sessions may include access to a laptop, projector and whiteboard or flipchart. A digital recorder will also be required to record sessions for fidelity checks.

Health and Safety Issues

Researcher Safety Issues

The research will be conducted in NHS settings during normal working hours. The field supervisor or another qualified clinician will co-facilitate group sessions. The research will adhere to procedures outlined within GG&C NHS safe working policies. A health and safety form has been submitted to the University of Glasgow for approval prior to applying for research ethics approval (Appendix A).

Participant Safety Issues

The researchers will be trained in Good Clinical Practice and NHS GG&C patient health and safety policy will apply throughout the duration of the study. Participants may experience distress during the study, have imminent need for support or disclose risk to or from either participants or the person with dementia. Confidentiality and its boundaries will be discussed with participants. Contacts of helpful services and advice on how to seek support if participants experience distress will be provided. Should any of the above happen, the researcher will initially contact the field supervisor of the study and will inform appropriate staff (e.g. GP, social services, other clinician) (Appendix A).

Ethical Issues

Research ethics approval will be sought from the West of Scotland Research Ethics Committee. It will be necessary to ensure that participants provide informed consent (to participate in the study and for the groups to be audio-recorded) and that the study follows ICH-GCP guidelines with regards to these procedures.

Risks of being in a group might include group member breaching confidentiality and causing distress to other group members. Therefore, at the start of each group a set of ‘rules’ will be constructed with participants to including no obligation to share personal information, a confidentiality agreement (i.e. what is said in the group, remains in the group) and encouraging mutual respect (i.e. notice how what others say affects you and allow for others opinions).

Confidentiality of participants will be ensured throughout the study and data will be kept in a safe and secure location for the appropriate length of time following the study. All outcome measures and participant feedback will remain anonymous by allocating a study number to each participant. A hardcopy of the numbers assigned to each participant, containing patient names, will be kept in a locked cabinet on NHS property. The electronic database including raw data will be kept on an NHS computer drive.

Financial Issues

Funds will be necessary for project materials and an application has been submitted to the University of Glasgow together with this proposal (Appendix B).

Timetable

Research ethics application to be submitted to the Research Ethics Committee (31st July 2016). See figure 2 for more details.

Practical Applications

If the outcomes of this project are promising this will contribute to the developing ACT evidence base for carers of people with dementia. The results of this feasibility study would inform the design and delivery of a future RCT study. It is also hoped that the results from this project may be accepted for publication in a relevant journal.

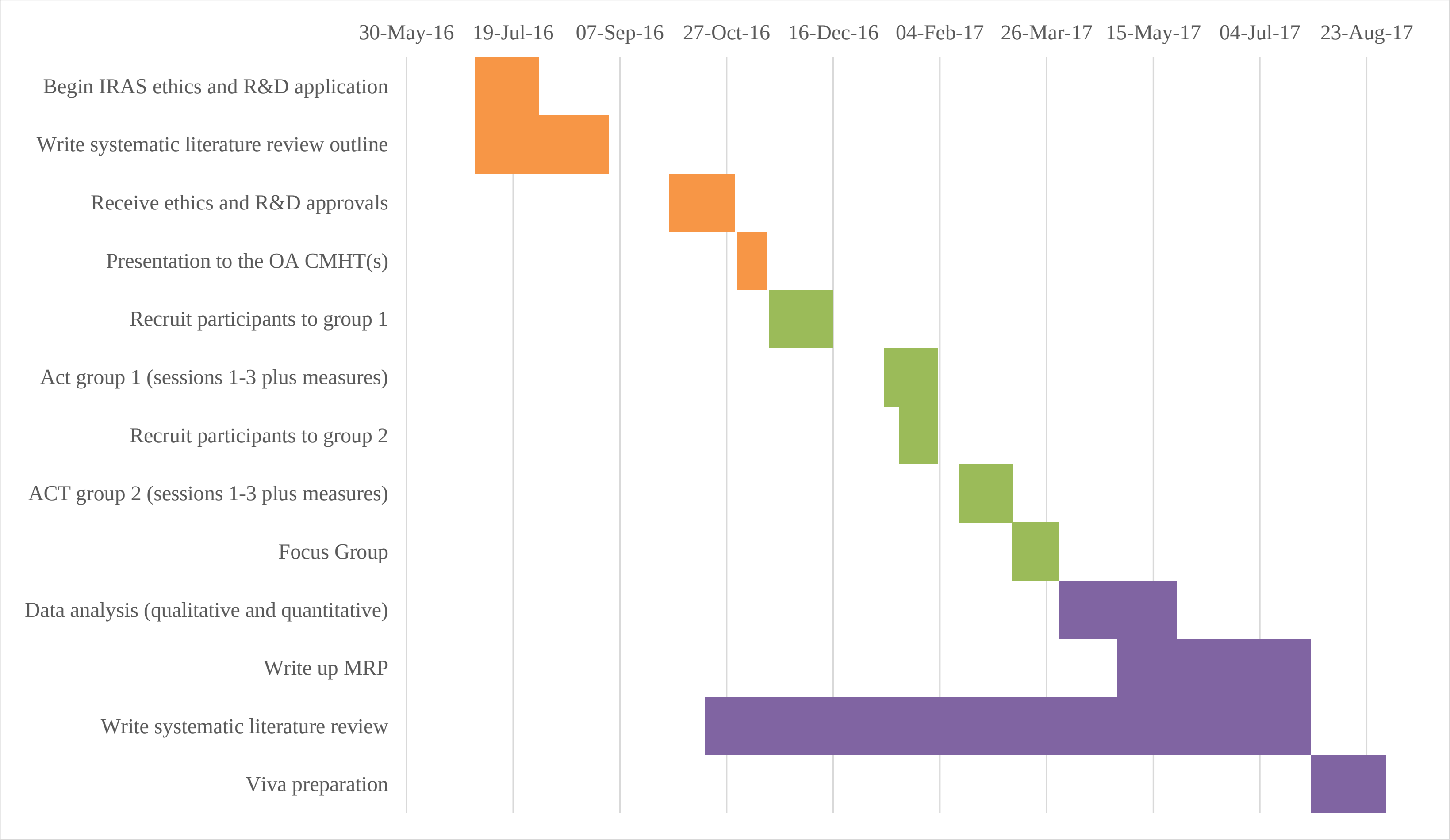

Figure 2. Project Timeframe.

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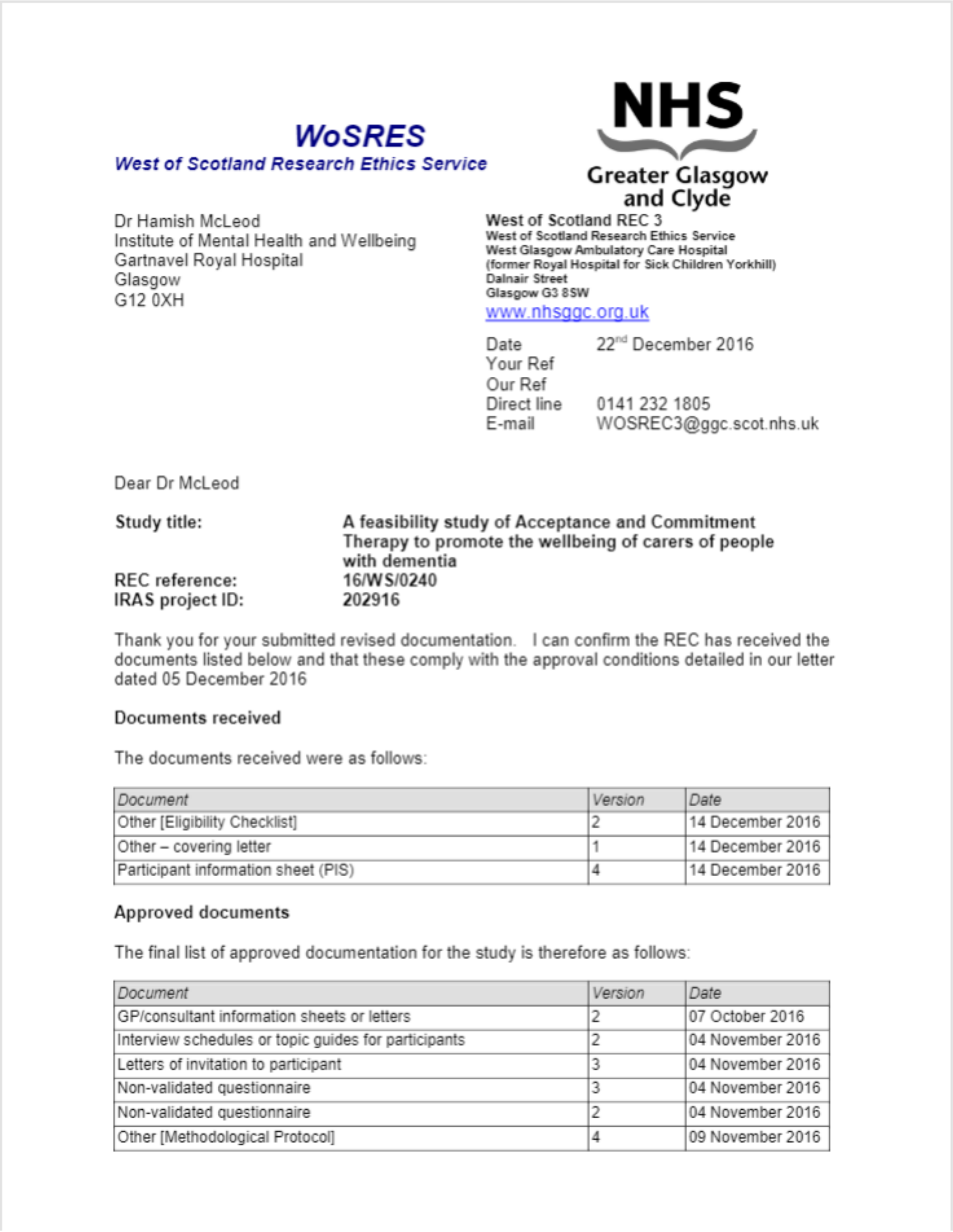
Appendix D. Logic Model for ACT to promote wellbeing of Carers of People with Dementia.

Problem Statement	Resources	Activities	Carer Outcomes	NHS Treatment Delivery Outcomes
• Carers of people with dementia are more likely to experience stress and burnout associated with being a carer, reduced wellbeing, and increased healthcare needs.	• Trial therapists/group facilitators. • NHS support for recruitment and delivery of the ACT group intervention.	• Delivery of 2 ACT groups to determine feasibility. • Process evaluation of the ACT group implimentation. • Analysis of ACT group model fidelity, effectiveness, and acceptability.	• Population: a) What are the numbers of potential participants identified who fulfil eligibility criteria? b) What proportion of potential participants provide fully informed consent to participate in the study? c) What are participants' baseline levels of psychological flexibility, flourishing, and carer burden? • Intervention: d) Will the ACT group intervention be acceptable to CPwD? 1. What proportion of participants are retained throughout the intervention? 2. What feedback do participants provide regarding their experiences of the group? e) Can the intervention be delivered with fidelity? • Outcomes: f) What differences occur between pre- and post- measures of psychological flexibility, flourishing, and carer burden? g) How helpful and effective do participants evaluate the group to be? h) What are the rates of retention at follow-up? i) Are there identifiable features of those participants that drop out of the group or are lost to follow-up?	• Knowledge regarding feasibility to inform further research e.g. pilot study.

Appendix 2.2 NHS Ethics and R&D Approval Letters



WoSRES
West of Scotland Research Ethics Service

NHS
Greater Glasgow
and Clyde

Dr Hamish McLeod
Institute of Mental Health and Wellbeing
Gartnavel Royal Hospital
Glasgow
G12 0XH

West of Scotland REC 3
West of Scotland Research Ethics Service
West Glasgow Ambulatory Care Hospital
(former Royal Hospital for Sick Children Yorkhill)
Dalnair Street
Glasgow G3 8SW
www.nhsggc.org.uk

Date 22nd December 2016
Your Ref
Our Ref
Direct line 0141 232 1805
E-mail WOSREC3@ggc.scot.nhs.uk

Dear Dr McLeod

Study title: **A feasibility study of Acceptance and Commitment Therapy to promote the wellbeing of carers of people with dementia**
REC reference: **16/WS/0240**
IRAS project ID: **202916**

Thank you for your submitted revised documentation. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 05 December 2016

Documents received

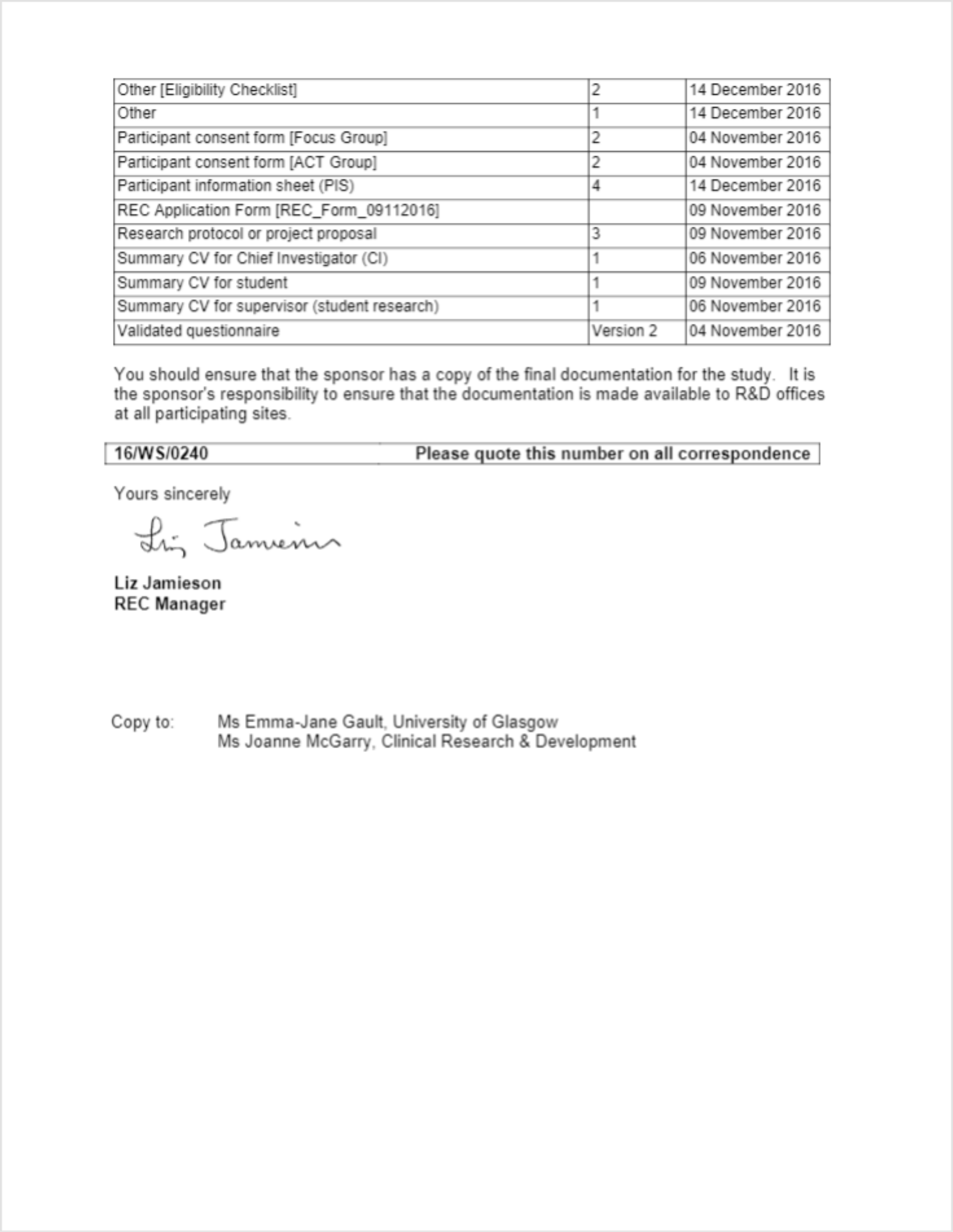
The documents received were as follows:

Document	*Version*	*Date*
Other [Eligibility Checklist]	2	14 December 2016
Other – covering letter	1	14 December 2016
Participant information sheet (PIS)	4	14 December 2016

Approved documents

The final list of approved documentation for the study is therefore as follows:

Document	*Version*	*Date*
GP/consultant information sheets or letters	2	07 October 2016
Interview schedules or topic guides for participants	2	04 November 2016
Letters of invitation to participant	3	04 November 2016
Non-validated questionnaire	3	04 November 2016
Non-validated questionnaire	2	04 November 2016
Other [Methodological Protocol]	4	09 November 2016



Other [Eligibility Checklist]	2	14 December 2016
Other	1	14 December 2016
Participant consent form [Focus Group]	2	04 November 2016
Participant consent form [ACT Group]	2	04 November 2016
Participant information sheet (PIS)	4	14 December 2016
REC Application Form [REC_Form_09112016]		09 November 2016
Research protocol or project proposal	3	09 November 2016
Summary CV for Chief Investigator (CI)	1	06 November 2016
Summary CV for student	1	09 November 2016
Summary CV for supervisor (student research)	1	06 November 2016
Validated questionnaire	Version 2	04 November 2016

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

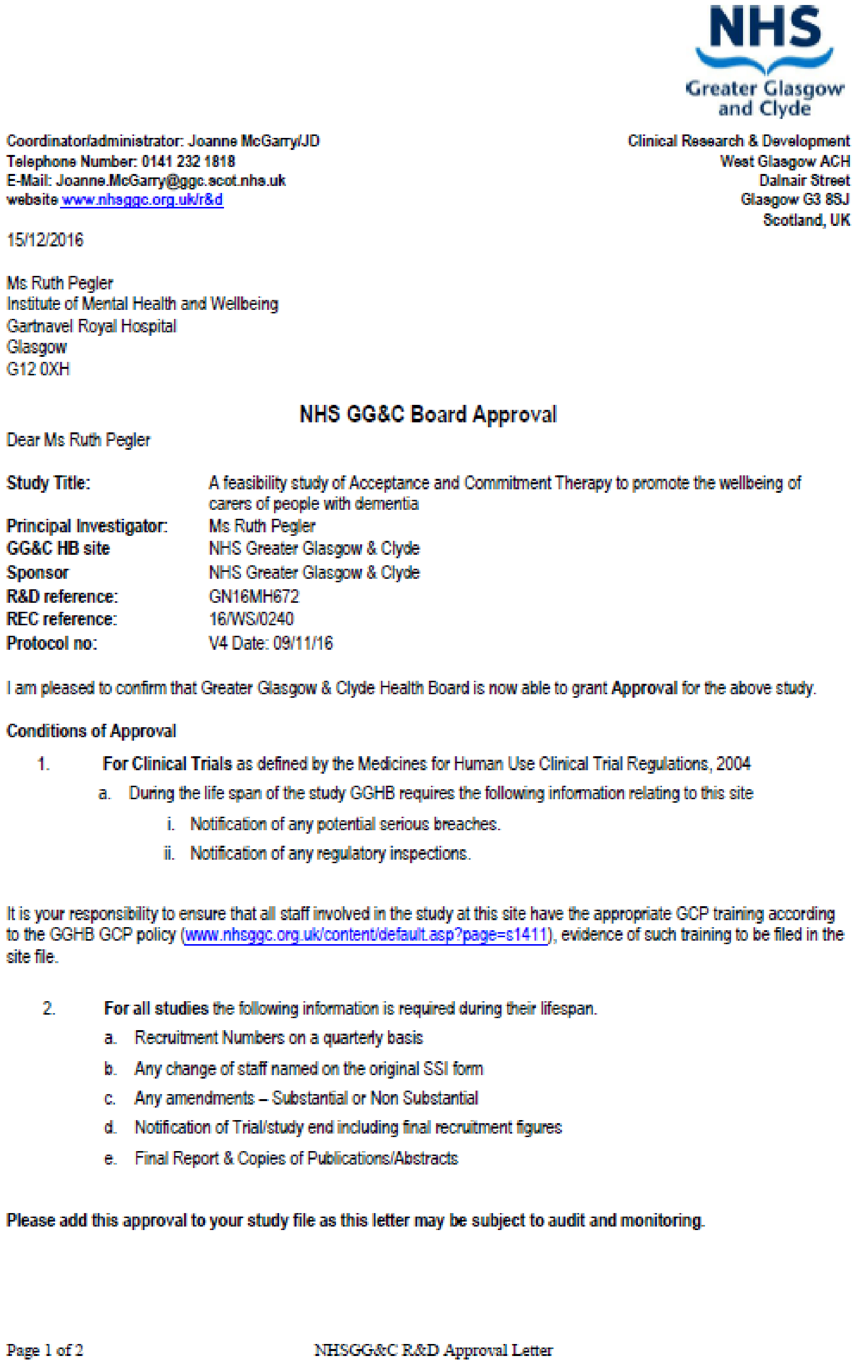
16/WS/0240 **Please quote this number on all correspondence**

Yours sincerely

Liz Jamieson

Liz Jamieson
REC Manager

Copy to: Ms Emma-Jane Gault, University of Glasgow
Ms Joanne McGarry, Clinical Research & Development



NHS
Greater Glasgow
and Clyde

Coordinator/administrator: Joanne McGarry/JD
Telephone Number: 0141 232 1818
E-Mail: Joanne.McGarry@ggc.scot.nhs.uk
website www.nhsggc.org.uk/r&d

Clinical Research & Development
West Glasgow ACH
Dalnair Street
Glasgow G3 8SJ
Scotland, UK

15/12/2016

Ms Ruth Pegler
Institute of Mental Health and Wellbeing
Gartnavel Royal Hospital
Glasgow
G12 0XH

NHS GG&C Board Approval

Dear Ms Ruth Pegler

Study Title: A feasibility study of Acceptance and Commitment Therapy to promote the wellbeing of carers of people with dementia
Principal Investigator: Ms Ruth Pegler
GG&C HB site NHS Greater Glasgow & Clyde
Sponsor NHS Greater Glasgow & Clyde
R&D reference: GN16MH672
REC reference: 16/WS/0240
Protocol no: V4 Date: 09/11/16

I am pleased to confirm that Greater Glasgow & Clyde Health Board is now able to grant **Approval** for the above study.

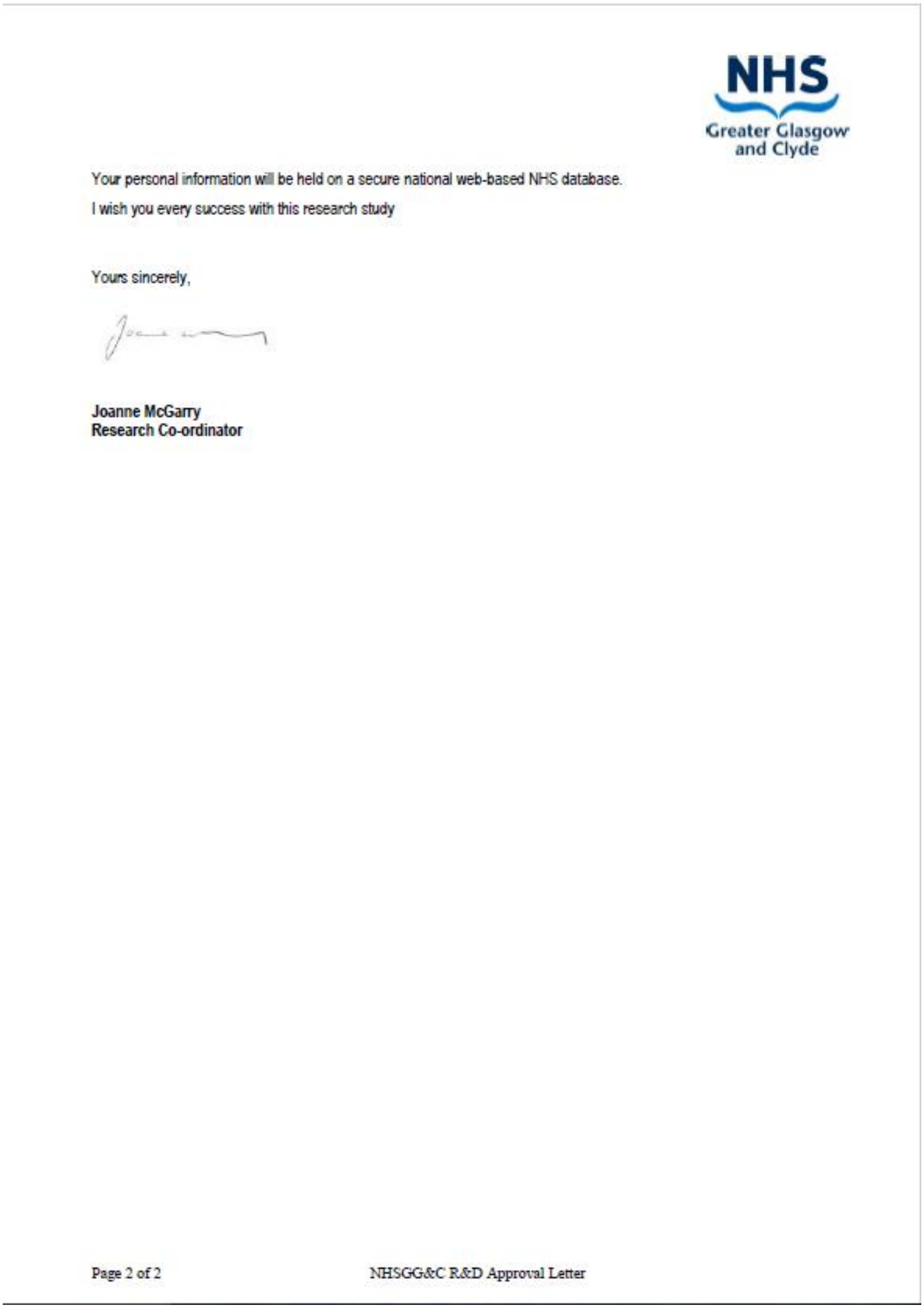
Conditions of Approval

1. **For Clinical Trials** as defined by the Medicines for Human Use Clinical Trial Regulations, 2004
   a. During the life span of the study GGHB requires the following information relating to this site
      i. Notification of any potential serious breaches.
      ii. Notification of any regulatory inspections.

It is your responsibility to ensure that all staff involved in the study at this site have the appropriate GCP training according to the GGHB GCP policy (www.nhsggc.org.uk/content/default.asp?page=s1411), evidence of such training to be filed in the site file.

2. **For all studies** the following information is required during their lifespan.
   a. Recruitment Numbers on a quarterly basis
   b. Any change of staff named on the original SSI form
   c. Any amendments – Substantial or Non Substantial
   d. Notification of Trial/study end including final recruitment figures
   e. Final Report & Copies of Publications/Abstracts

Please add this approval to your study file as this letter may be subject to audit and monitoring.



NHS
Greater Glasgow
and Clyde

Your personal information will be held on a secure national web-based NHS database.

I wish you every success with this research study

Yours sincerely,

Joanne McGarry
Research Co-ordinator

Appendix 2.3 Overview of ACT Group Sessions

SESSION ONE	**KEY ACT INTERVENTIONS**
Part 1	
1. Welcome and Introductions	Mindfulness warm-up exercise
2. Overview of the training	Tap analogy Fred the Bus Driver
Part 2	
3. Introduction to mindfulness	Raisin exercise;
TEA/COFFEE BREAK	
	Brief mindfulness of body and breath
4. Introduction to values-based action	Values card sort; Lost in the Jungle metaphor; define one value and translate into specific actions for the next week
Part 3	
5. Presentation of rationale for the program	Two sheets of paper technique
6. Discussion of home practice assignments	Home practice handout; environmental reminders

SESSION TWO	**KEY ACT INTERVENTIONS**
Part 1	
1. Brief Welcome back and opening mindful practice	Mindfulness of breath; noticing thoughts and feelings and allowing them to come and go
2. Home practice review	Pairs and group discussion
3. Presentation of training rationale	“Passengers on the bus” metaphor
Part 2	
4. Untangling from thought barriers to valued action	Self-reflection on unhelpful thought content; cartoon voices technique; physical demonstration of fusion/defusion; thoughts on screen exercise
TEA/COFFEE BREAK	
5. Mindfulness of mood/emotion	Physicalizing exercise
Part 3	
1. Defining values and values-based goal and action planning	Construction of two-week values-based goal and action plan
2. Discussion of home practice assignments	Home practice handout; environmental reminders; public commitment to one value-based goal

SESSION THREE	**KEY ACT INTERVENTIONS**
Part 1	
3. Welcome back	Two-skills diagram/Bus analogy picture
4. Opening mindfulness practice	Mindfulness of body and breath
5. Home practice review	Pairs and group discussion
6. Assessing value consistency	Self-reflection on value-consistent and –inconsistent actions over the past two weeks
Part 2	
7. Mindfulness of thought and feeling	Thoughts on clouds exercise; physicalizing exercise; contacting the resilient “observer” perspective
TEA/COFFEE BREAK	
Part 3	
8. Values-based goal and action planning	Short-term, medium-term, and long-term values-based goal-setting exercise; value-based action map
9. Recommendations for continued practice	Home practice handout; top tips for building a valued life
10. Final personal reflections on the training	Feedback, post-baseline questionnaires, and satisfaction questionnaire, invite to focus group.

Appendix 2.4 Focus Group Semi-Structured Interview Schedule

Version 2.1: Date: 12/04/2017

FOCUS GROUP SEMI-STRUCTURED INTERVIEW PROTOCOL

Title of project: A feasibility study of Acceptance and Commitment Therapy to promote the wellbeing of carers of people with dementia.

Introduction: Thank you for agreeing to participate in this study and to come along today to give us more information about your experience of attending the ACT group sessions. The purpose of today is to have the opportunity to hear from you in more detail about what it was like for you to attend the ACT groups (Woodlands and Goldenhill). Today we have 2 hours to discuss how you found the groups and so I will be guiding our discussions so that we can make the most of this time. Please feel free to discuss with each other as well as answering me directly. We are interested to find out what it was like from all of your perspectives.

Hopes and expectations

- **So to begin, I wonder if you could think back to before the group started when you had not yet meet each other or the group facilitators. Can you think about any hopes, expectations, or worries about what the group would be like?**

How was attending the group?

- **Practicalities: How did you find travelling to the group sessions? In terms of your role as a carer, how did you make time to come to the groups? Were there any practical arrangements that you needed to make? How did you find the timing of the group sessions? (time of day, day of the week, spacing between sessions)**
- **What were your thoughts about completing the questionnaires?**
- **Research into interventions like this group sometimes involves participants being randomly picked to attend the group sessions or have ‘treatment as usual’ or no group. How would you feel about this?**

- **Experience of ACT approach: What was your experience of being in the group like? What are your thoughts on sharing your experiences with others in a group setting? What did you think about the activities that you were asked to do during the group (mindfulness, worksheet tasks, discussion etc.)? What did you think about the pacing of the group sessions? What are your thoughts about the approach of the group facilitators?**
- **Was there any part of the group that made you feel uncomfortable or that you did not think was relevant to your role as a carer for your partner/family member?**

How helpful was the group?

- **Were there parts of the group that you thought were particularly helpful?**
- **Were there any parts of the group that you found less helpful?**
- **Was there anything that you think would have improved your experience of the group? Was there anything that you would have liked to have been added to the group?**
- **What do you think you have taken from your experience of the groups?**
- **Having attended the group have you noticed any differences in:**
    - **Your attitudes or thoughts as a carer?**
    - **Your actions or the things you do?**
    - **The way you relate to yourself?**

Is there anything that you would like to add that we have not covered about your experience of attending the ACT groups?

Appendix 2.5 Acceptability Questionnaire

Version 2: Date: 04/11/2016

ACT GROUP EVALUATION FORM

Title of project: A feasibility study of Acceptance and Commitment Therapy to promote the wellbeing of carers of people with dementia.

Participant identification number for this trial:

Date:___________________________________

We are interested to understand more about your experience of attending the ACT group sessions and value your opinions.

Please take your time to read and respond to both the rating scales and the written feedback sections.

Please mark (with a circle, tick, or cross) which number best represents your experience.

I found the group sessions helpful

1	2	3	4	5	6	7
Strongly disagree			Neither agree / disagree			Strongly agree

The content of the group was what I had expected

1	2	3	4	5	6	7
Strongly disagree			Neither agree / disagree			Strongly agree

It was easy for me to attend the group

1	2	3	4	5	6	7
Strongly disagree			Neither agree / disagree			Strongly agree

I would recommend this group to other carers

1	2	3	4	5	6	7
Strongly disagree			Neither agree / disagree			Strongly agree

Were there any parts of the group that were particularly helpful for you?

Were there any parts of the group that you found less helpful?

Was there anything that you think would improve the group?

Appendix 2.6 Free-text Response to Acceptability Questionnaire

Participant	Helpful Parts	Less Helpful Parts	Improvement Suggestions
1	• The mindfulness sessions. • The analogy of the bus. • The tip of noticing that you are thinking.	The seating and worktop made it difficult – could have been improved with a “horseshoe” desk arrangement.	Longer sessions to fully get into the exercises
2	• The welcome and introductions from both Eleni and Ruth • The leadership skills when we exercised mindfulness • The information presented clearly and repeated to refresh us at the beginning of each session • The respect and understanding of our lives	The visual slides were too small or out of view	Improve visual aids
5	• Being introduced to the art of mindfulness • Raising awareness of self-helping. • *I felt I got a lot out of all sessions – so no negative thoughts about any of the sessions.* • *As this was a pilot, I found it was delivered very effectively and with great respect to all of the participants.*	*I felt I got a lot out of all sessions – so no negative thoughts about any of the sessions.*	• *As this was a pilot, I found it was delivered very effectively and with great respect to all of the participants.* • Perhaps extending the length of the course would be beneficial with some sort of follow up.
6	Mindfulness exercises, help me deal with my thoughts and feelings	No.	No.

7	Mindfulness exercises	No everything was very helpful	No.
8	• Realisation that I'm not alone and it's good to share experiences, good/bad, happy/sad. • *Everything was beneficial to me – if not right away then definitely on reflection.* • *It was lovely and relaxed atmosphere. Knowing everything was confidential was a huge bonus. Would love to have feedback on how the group was perceived.*	No – *everything was beneficial to me – if not right away then definitely on reflection.*	No – *it was lovely and relaxed atmosphere. Knowing everything was confidential was a huge bonus. Would love to have feedback on how the group was perceived.*
9	• It was great to be able to be part of a group where the others shared similar experiences to oneself. • *The group were all very respectful of each others feelings and responsibilities.* • *The content of the sessions was well thought out and I think the entire group benefited from attendance.*	No – *the group were all very respectful of each others feelings and responsibilities.* *The content of the sessions was well thought out and I think the entire group benefited from attendance.*	Not really. I think a group meeting on a regular basis would be beneficial for all.
10	• Served as a helpful reminder to "live in the present moment". • Shared experiences.	Sometimes difficult to maintain focus on subject being discussed (More to do with participants).	Think the ACT group outcome measures questions could be "worded" better. Some questions I did not answer.
11	• The bus analogy • The leaves on the stream analogy • The bulls eye diagram		The teaching of the New Testament is at least as helpful as other Eastern religion. E.g. Matthew 5-7. Galations 6 Romans 12.

16	• General assurance that as a carer it is perfectly normal to feel stressed from time to time. • *Course was constructive and meaningful.*	Cannot point to anything of significance. *Course was constructive and meaningful.*	Perhaps tailoring to focus on participants who are at different stages as carers for dementia sufferers, although acknowledge this would be difficult i.e. Participants are caring for relatives at different stages of dementia.
17	• Content good. • Timing good. • Enjoyable.		• Not experienced enough to comment. • Maybe time to think and evaluate (Stamped Addressed Envelope)
19	• The mindfulness exercises. • The shared experiences of others in the group.		
22	• The mindfulness exercises, particularly the leaves on the stream exercise. Found that one the easiest to visualise and use. • Talking to and listening to other carers. • Learning how to deal with difficult thoughts.	No.	Can’t think of anything at the moment.
Italics denote that relevant comment was written in response to another question			

Appendix 2.7 ACT Adherence Measure Ratings

ACT Therapist Stance	Assessor 1	Assessor 2
Encourage the client to talk about their experiences?	2	2
Give general praise for the client's past efforts?	2	2
Give encouragement for future client efforts?	2	2
Make summary statements?	3	3
Ask for client feedback about session?	4	3
Listen actively?	3	2
Pace the session appropriately?	2	3

ACT Consistent Strategies/behaviours	Assessor 1	Assessor 2
Developing acceptance and willingness / undermining experiential control	*2*	2
Undermining cognitive fusion	3	3
Getting in contact with the present moment	4	2
Distinguishing the conceptualized self from observer-self	1	2
Defining valued life directions	3	4
Building patterns of committed action	3	2

Competence	Assessor 1	Assessor 2
Knowledge of treatment	3	2
Skill in delivering treatment	3	2
Appropriate application of treatment components within the context of the session	3	3
Relationship with the client	4	3
Overall performance	3	2