

ORIGINAL RESEARCH

Supported cognitive-behavioural therapy self-help versus treatment-as-usual for depressed informal caregivers of stroke survivors (CEDArS): feasibility randomised controlled trial

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Abstract

Demands placed on informal caregivers can result in an increased likelihood of experiencing common mental health difficulties that may affect their ability to undertake the caring role. Currently, however, few evidence-based interventions have been specifically developed for informal caregivers and available interventions are difficult to access. The Improving Access to Psychological Therapies (IAPT) programme aims to improve access to evidence-based psychological therapies for all groups and may therefore present an opportunity to meet informal caregiver needs. Located within the MRC Complex Intervention Framework, a Phase II feasibility randomised controlled trial (RCT) examines key methodological, procedural and clinical uncertainties associated with running a definitive Phase III RCT of an adapted written cognitive behavioural therapy (CBT) self-help intervention for informal caregivers of stroke survivors. Recruitment was low despite different recruitment strategies being adopted, highlighting significant challenges moving towards a Phase III RCT until resolved. Difficulties with study recruitment may reflect wider challenges engaging informal caregivers in psychological interventions and may have implications for IAPT services seeking to improve access for this group. Further attempts to develop a successful recruitment protocol to progress to a Phase III RCT examining effectiveness of the adapted CBT self-help intervention should be encouraged.

Key learning aims

After reading this article, readers should be able to:

- (1) Consider key feasibility issues with regard to recruitment and attrition when running a randomised controlled trial of an adapted written cognitive behavioural therapy (CBT) self-help intervention for informal caregivers of stroke survivors.
- (2) Understand potential barriers experienced by an informal caregiving population to accessing psychological interventions.
- (3) Appreciate implications for clinical practice to enhance access to IAPT services and low-intensity CBT working with an informal caregiver population.

Keywords: CBT; cultural adaptation; depression; primary care; self-help

Introduction

Stroke commonly occurs in people from late middle age and represents a leading cause of mortality and disability worldwide (Johnson *et al.*, 2019). Significant physical, emotional, cognitive and behavioural impairment associated with stroke places large demands on stroke survivors (Lui and Nguyen, 2018), alongside wider society and the economy (Dunbar *et al.*, 2018; Johnson *et al.*, 2019). Given these long-term impairments, support is often provided by informal caregivers in the home (Sumathipala *et al.*, 2012). However, the provision of informal care is associated with a range of personal and societal costs. Costs include high caregiving burden (Oliva-Moreno *et al.*, 2018; Pucciarelli *et al.*, 2018), reductions in paid employment and associated financial difficulties (Andrew *et al.*, 2015), social isolation (Lou *et al.*, 2017), loss of self-identity (Knowles *et al.*, 2016) and reduced engagement with valued activities (Jellema *et al.*, 2019). Provision of informal care is also associated with greater risk of poor physical health (Hiel *et al.*, 2015) and mental health (Haley *et al.*, 2015) in informal caregivers themselves, with pooled prevalence rates of 40.2 and 21.4% found for depressive and anxiety-related symptoms, respectively (Loh *et al.*, 2017). The need for evidence-based psychological interventions to support the long-term mental health needs of informal caregivers of stroke survivors is therefore justified. However, the long-term mental health needs of informal caregivers have been neglected (Silva *et al.*, 2013; Simon *et al.*, 2009).

Despite evidence-based psychological interventions for common mental health difficulties existing, there is a large psychological treatment gap globally for both depression (Thornicroft *et al.*, 2017) and anxiety disorders (Alonso *et al.*, 2018). Across Europe, less than 30% of people with mental health difficulties access treatment (Wittchen *et al.*, 2011). To address this treatment gap, the Improving Access to Psychological Therapies (IAPT) programme has been implemented across England [Clark, 2011; National Collaborating Centre for Mental Health (NCCMH), 2019]. In the IAPT programme, access for the treatment of mild-to-moderate common mental health difficulties is enhanced through the delivery of psychological therapies within a stepped-care service delivery model (van Straten *et al.*, 2015). Informed by guidance from the National Institute for Health and Care Excellence (NICE, 2009, 2013), patients are initially assessed and receive low-intensity cognitive behavioural therapy (LICBT) at Step 2 of the stepped-care model (Clark, 2018), with those not recovering stepped-up to an evidence-based high-intensity intervention. LICBT intervention delivery is based on CBT self-help resources provided through a range of written materials or digital technologies (Farrand and Woodford, 2013). With guided LICBT, support is provided face-to-face or over the telephone by a psychological wellbeing practitioner (PWP) workforce (Clark, 2018), with a systematic review demonstrating higher effect sizes for supported rather than self-administered self-help (Farrand and Woodford, 2013).

Guided LICBT therefore represents a flexible way to deliver evidence-based psychological therapies, making it well suited to address barriers to treatment experienced by informal caregivers given demands of the caregiving role (Woodford *et al.*, 2014; Woodford *et al.*, 2018). Indeed, a review of interventions for informal caregivers of stroke survivors recommended telephone or internet-administered support to increase access for this population (Bakas *et al.*, 2014). However, evidence indicates that adapting LICBT interventions to represent the needs of specific populations is required to improve acceptability and engagement with adaptations made to interventions for Armed Forces veterans (Farrand *et al.*, 2019), people with dementia (Farrand *et al.*, 2016) and parents of children treated for cancer (Wikman *et al.*, 2018). Failing to adapt LICBT interventions for specific populations may also account for smaller effect sizes experienced by people with chronic health conditions compared with an adult mental health population (Beatty and Lambert, 2013; Farrand and Woodford, 2015), whereas tailoring psychological interventions for informal caregivers resulted in interventions being more effective than non-tailored interventions (Bakas *et al.*, 2014). This is of particular importance

given that few psychological therapies have been adapted to accommodate the increased demands placed on informal caregivers (Krevers and Öberg, 2011).

Following the Medical Research Council (MRC) complex interventions framework (Craig *et al.*, 2008), a written CBT self-help intervention for depression in informal caregivers of stroke survivors was developed (Woodford *et al.*, 2014; Woodford *et al.*, 2018). The CBT self-help intervention was designed to be supported by PWPs for delivery within IAPT services (Clark, 2011; Clark, 2018). A Phase II feasibility randomised controlled trial (RCT; Eldridge *et al.*, 2016) was conducted to examine methodological and procedural uncertainties to inform decisions to progress to a definitive Phase III trial (Thabane *et al.*, 2010). Specific uncertainties include: (1) recruitment; (2) attrition; and (3) collection of outcome measurements as per those adopted within the IAPT programme (Clark, 2018).

Method

Trial design

This was a single-blind parallel group feasibility RCT (Craig *et al.*, 2008), comparing supported written CBT self-help for depressed informal caregivers of stroke survivors with a treatment-as-usual (TAU) control group. It was reported in line with the CONSORT extension for randomised pilot studies (Eldridge *et al.*, 2016). The full study protocol has been published (Woodford *et al.*, 2014) with no methodological or procedural changes made after trial commencement.

Participants

Eligible participants were: (a) self-identified informal caregivers of stroke survivors; (b) caring for a stroke survivor who had been at home for a minimum of 2 months following most recent stroke episode; (c) aged 16 years or over; (d) met criteria for major depressive disorder as determined by the Clinical Interview Schedule (CIS-R; Lewis *et al.*, 1992); (e) scored between 10 and 22 on the PHQ-9; and (f) able to read English (see Appendix 1 in Supplementary material for baseline characteristics). Non-eligible participants were: (a) with a self-identified severe and enduring mental health difficulty; (b) currently misusing alcohol, prescribed medication or illegal drugs; (c) acutely suicidal; or (d) receiving another formal psychological therapy.

Setting

Participants were recruited via primary care services, specialist stroke healthcare settings and community organisations. The CBT self-help intervention was delivered by PWPs within *Outlook Southwest* and *Steps2Wellbeing* IAPT Services operating within Cornwall and Dorset in southwest England.

Recruitment

Informed by an effective strategy for the recruitment of informal caregivers of people with dementia (Whitebird *et al.*, 2011), participants were recruited via the following routes.

Primary care

Practice staff searched General Practice electronic case records for stroke survivors and manually identified known informal caregivers. Study information packs were sent to all identified informal caregivers via the post with informal caregivers able to reply to the research team via reply slip or telephone. General practitioners (GPs) were also able to refer informal caregivers directly and study posters were displayed in General Practice reception areas.

Specialist stroke care settings

Acute and community-based stroke clinical teams (e.g. acute stroke units, stroke rehabilitation units) approached informal caregivers within these settings and provided study information packs. Interested informal caregivers could either consent to the clinical team passing their contact details to the study team or reply to the research team directly using a reply slip or the telephone.

Community outreach

Study posters and flyers were displayed in community-based stroke and informal caregiver charities (e.g. Stroke Association) or within their newsletters and social media.

In each setting, potential participants were provided with a study information pack including an invitation letter, patient information sheet and anonymised reply slip to record reasons for non-participation.

Procedure

A researcher spoke to all interested informal caregivers, provided additional study information and gained verbal consent from potential participants agreeing to be telephone-screened. If eligible, full written consent was obtained with a full eligibility screen conducted over the telephone or face-to-face. Participants then completed clinical outcome measurements representing the baseline.

Randomisation, allocation concealment and blinding

A web-based external randomisation service located at the Peninsula Clinical Trials Unit was used to randomly allocate participants to either supported CBT self-help or treatment as usual. Minimisation was used to ensure balance across study sites, depression score at baseline and gender. To preserve blinding, allocation details were emailed to a researcher not otherwise associated with the study who informed participants of the study arm they were allocated. Allocation details were also emailed to the PWP the participant had been allocated to. A researcher remaining blind to group allocation collected and analysed all clinical and feasibility outcome data (Woodford *et al.*, 2014).

Interventions

Written CBT self-help

Participants received an assessment session (35 minutes) with a PWP from a participating IAPT service in Cornwall or Dorset. All study PWPs had completed the IAPT national curriculum for the education of PWPs (Richards *et al.*, 2011a,b) from an accredited training provider. A further a 1-day training session related to specific factors associated with the adapted CBT self-help intervention was delivered by study authors (P.F. and J.W.) and involved an informal caregiver of a stroke survivor alongside a stroke healthcare professional. Following the initial assessment session, the CBT self-help workbook was introduced (Woodford and Farrand, 2013). The workbook was developed specifically for informal caregivers of stroke survivors and was informed by previous qualitative research exploring the difficulties experienced by informal caregivers with elevated symptoms of depression and anxiety (Woodford *et al.*, 2018). This workbook introduced three single stand LICBT interventions: behavioural activation, problem solving and goal setting (Bennett-Levy *et al.*, 2010). The single LICBT intervention best suited to the main presenting difficulty was chosen collaboratively between the PWP and informal caregiver. At the end of treatment all participants received relapse

prevention adapted for the population. During support sessions of between 25 and 35 minutes, informal caregivers were provided with the workbook alongside guidance concerning use between sessions. Dependent on informal caregiver preference, assessment and support sessions were provided face-to-face or over the telephone. Consistent with the IAPT programme, the number of support sessions was determined collaboratively during case-management supervision (Richards, 2010). Participants could receive up to 12 support sessions, which is higher than the number commonly received for adults within the IAPT programme (Clark, 2018; NHS Digital, 2019). Routine case-management and clinical skills supervision was supplemented by an additional monthly group clinical supervision session (45 minutes) specific to the caregiver intervention provided by a PWP clinical educator trained in the intervention.

Control

This was TAU where participants received usual care, for example support provided by a GP or other healthcare provider.

Outcomes

Consistent with the aims of a feasibility RCT, primary outcomes associated with study recruitment and attrition were examined to inform the potential to progress to a definitive RCT (Craig *et al.*, 2008; Eldridge *et al.*, 2016). *A priori* progression criteria to inform whether or not to proceed to a future definitive trial were not set in the present study. Clinical outcome measurements were included to examine the feasibility of clinical outcomes data collection, including severity of depression (PHQ-9; Kroenke *et al.*, 2001) and anxiety symptoms (GAD-7; Spitzer *et al.*, 2006), functional impairment (WSAS; Mundt *et al.*, 2002) and caregiver burden (CBS; Elmstahl *et al.*, 1996). Additionally, the number, length and frequency of support sessions was recorded, alongside clinical outcomes per support session in accordance with the IAPT minimum data set (NCCMH, 2019). Additional clinical outcome measures addressing wider impacts were also collected (Appendix 2 in Supplementary material).

Sample size

As per standard practice in pilot RCTs, no formal power calculation was undertaken (Arain *et al.*, 2010). The recommended sample size of 30 participants per arm for pilot RCTs was used (Browne, 1995), consistent with the median sample size found in pilot RCTs (Billingham *et al.*, 2013).

Statistical analysis

Participant flow data were used to calculate recruitment and attrition rates. Odds ratios were calculated with 95% confidence intervals to compare attrition rates between study arms. All analysis was undertaken per-protocol. Descriptive summaries (means and standard deviations) for the PHQ-9, GAD-7, WSAS and CBS clinical outcomes are reported at baseline, and 4- and 6-month follow-up. Means and standard deviations are also reported for the number, length and frequency of support sessions.

Results

Participant flow

Recruitment flow into the study with reasons for exclusion at both initial and full screen are illustrated using a CONSORT diagram (Schulz *et al.*, 2010; see Fig. 1).

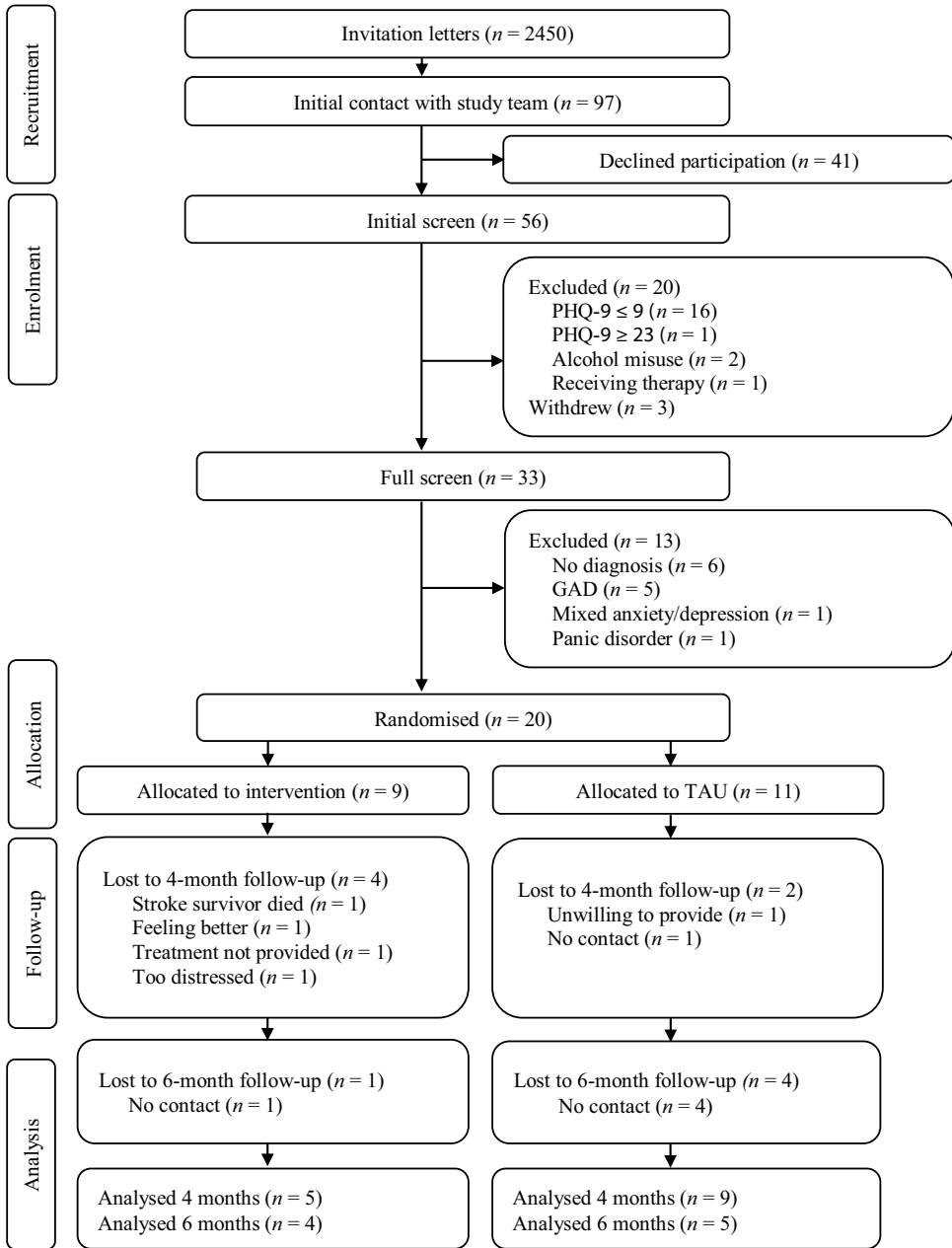


Figure 1. Consolidated Standards of Reporting Trials (CONSORT) flow diagram.

It cannot be known that community organisations distributed information packs to informal caregivers. Therefore, 284 information packs provided to community organisations are not included in the total number of invitation letters sent. Of the 2450 informal caregivers invited, 1% (20/2450) were randomised, with nine allocated to the intervention and 11 to the control (TAU). In total, 30% of participants (6/20) dropped out before 4-month post-randomisation follow-up (control: 2/11, 18%; intervention: 4/9, 44%). An odds ratio of 3.6 [95% confidence interval (CI): 0.48–27.11] indicated no difference in drop-out at 4-month follow-up.

Table 1. Reasons for non-participation

Area	Reasons reported	<i>n</i> (%)
Coping well	(a) Not experiencing low mood or depression (<i>n</i> = 123) (b) Stroke survivor required little support (<i>n</i> = 86) (c) Coping well with the caregiving role (<i>n</i> = 55)	303 (55)
Barriers accessing support	(a) Lack of time (<i>n</i> = 33) (b) Own poor physical health (<i>n</i> = 27) (c) Consider depression unrelated to the caregiving role (<i>n</i> = 14) (d) Not identifying as an informal caregiver (<i>n</i> = 12) (e) Consider main difficulty to be a lack of social care and practical support (<i>n</i> = 11)	183 (33)
Procedural	Mainly related to study procedural issues, including: (a) Response received from the stroke survivor not caregiver (<i>n</i> = 16) (b) Invitation incorrectly sent, e.g. wrong address (<i>n</i> = 15) (c) Stroke survivor deceased (<i>n</i> = 4)	44 (8)
No point in the research	Unable to see any benefit to themselves from study participation	3 (0.5)
No reason provided	Reason for non-participation form returned without a reason stated	22 (4.0)

Most frequently reasons provided only, therefore sample size (*n*) reported under reasons reported does not equal total sample size for each area.

At 6-month follow-up, a total of 55% participants (11/20) had dropped out of the study (control: 6/11, 55%; intervention: 5/9, 56%). An odds ratio of 1.04 (95% CI: 0.18–6.12) indicated no difference in drop-out at 6-month follow-up. Study arm status was disclosed to the researcher responsible for collecting data for 30% (6/11) of participants (disclosure from participant: 4/6, 67%; disclosure from PWP: 2/6, 33%).

Feasibility of recruitment

Randomisation rates for each source of recruitment were similar (General Practice: 15/2055, 0.7%; stroke healthcare settings: 2/395, 0.5%; community outreach: 3/284, 1%). A detailed breakdown of enrolment stage by source of recruitment is presented in Appendix 3 in Supplementary material.

Reasons for non-participation

Of the 2450 invitation packs distributed, 376 (15%) participants returned reasons for non-participation slip. In total, 555 individual reasons for non-participation were provided and categorised into four main areas (Table 1).

Participant characteristics

A summary of sociodemographic characteristics of informal caregiver participants and stroke survivors is presented in Appendix 1 in Supplementary material. Participants were predominantly female (*n* = 13, 65%); White British (*n* = 19, 95%) and the spouse or partner of the stroke survivor (*n* = 17, 85%). Mean age of participants was 63 years (*SD* = 10.3) and had been in the caregiving role for a mean of 8 years (*SD* = 9.3).

Clinical outcomes

Means and standard deviations for each of the main clinical outcomes (PHQ-9, GAD-7, WSAS and CBS) can be seen in Appendix 4 in Supplementary material. Means and standard deviations for additional clinical outcomes were also collected (Appendix 5 in Supplementary material). Given the small sample size, participant drop-out being different between trial arms, and the

Table 2. Variability in number, length and frequency of support sessions and individual session data^a

Session characteristics						
	Mean		SD		Range	
Number of treatment sessions	4.0		1.4		3.0–6.0	
Number of do not attends	0.5		1.0		0.0–2.0	
Total duration of treatment (weeks)	13.0		5.9		8.0–21.3	
Average length of treatment sessions (min)	30.8		1.0		30.0–32.0	
Clinical outcome measures						
	PHQ-9		GAD-7		WSAS	
	Mean (SD)	Range	Mean (SD)	Range	Mean (SD)	Range
Baseline	15.0 (4.2)	11.0–20.0	10.5 (3.9)	6.0–15.0	22.3 (10.3)	13.0–35.0
Initial assessment session	16.0 (8.3)	7.0–27.0	12.5 (5.2)	7.0–19.0	26.3 (7.9)	16.0–35.0
Final treatment session	10.3 (8.2)	4.0–24.0	7.0 (7.0)	2.0–19.0	21.0 (6.3)	16.0–29.0
4-months post-randomisation	6.3 (3.2)	4.0–11.0	3.0 (1.8)	1.0–5.0	14.4 (14.5)	0.0–27.5
6-months post-randomisation	5.8 (6.5)	0.0–15.0	4.5 (5.9)	0.0–13.0	15.3 (11.0)	6.3–30.0

Means, standard deviations (*SD*) and ranges reported to 1 decimal place. PHQ-9, Patient Health Questionnaire-9; GAD-7, Generalised Anxiety Disorder 7-item Scale; WSAS, Work and Social Adjustment Scale. ^aData are presented for four of the five participants who remained in the study at 4-months post-randomisation. Session data were not provided by the PWP of one of the five participants, therefore their data is not included in this table.

aims of a feasibility study, these results are presented for descriptive purposes only and should be interpreted with caution.

Variability in number, length and overall duration of support sessions and individual session data

Of the five participants in the intervention arm who remained in the study at 4-months post-randomisation, four had complete data on support sessions and the main clinical outcomes. Number, length and overall duration of assessment and support sessions alongside baseline, initial assessment, final treatment and follow-up data for the PHQ-9, GAD-7 and WSAS is presented for the four participants with complete follow-up data (Table 2). Participants received a mean number of 4 (*SD* = 1.4, range = 3–6) assessment and support sessions with mean session length of 30.8 minutes (*SD* = 1.0, range = 30–32). The mean overall duration of treatment was 13 weeks (*SD* = 5.9, range = 8.0–21.3). Investigation of the wide range for overall duration of treatment by the study team identified that PWPs were offering support sessions on a fortnightly basis, and in one case, the informal caregiver and PWP had difficulties in arranging support sessions around the informal caregiver's busy schedule.

At the initial assessment session, the mean PHQ-9 score was 16.0 (*SD* = 8.3, range 7.0–27.0). Scores indicating severe depression on the PHQ-9 were reported by one participant, accounting for the large *SD* and wide range in scores (Table 2).

The mean GAD-7 score at initial assessment was 12.5 (*SD* = 5.2, range = 7.0–19.0). Again, scores indicating severe anxiety on the GAD-7 were reported by one participant, accounting for the large *SD* and wide range in scores. By the final treatment session, the mean PHQ-9 score was 10.3 (*SD* = 9.5, range = 4.0–24.0), slightly above caseness as defined as a score of ≤ 9 . The mean GAD-7 score was 7.0 (*SD* = 7.0, range = 2–19), which was at caseness as defined by a GAD-7 score of ≤ 7 .

Discussion

Located within Phase II of the MRC Complex Interventions Framework (Craig *et al.*, 2008), this study examined the feasibility of conducting an RCT comparing an adapted CBT self-help

intervention for depressed informal caregivers of stroke survivors with treatment as usual. Results highlight significant challenges recruiting informal caregivers that need to be addressed prior to moving to a definitive Phase III (effectiveness) RCT. Given the feasibility study design, small sample size and participant drop-outs, clinical outcomes reported are solely for descriptive purposes and should be interpreted with caution.

Despite adopting multiple strategies to recruit informal caregivers into the present study, recruitment rates were low in all settings (General Practice, stroke specialist healthcare and community outreach). Although difficulties recruiting into depression trials are well documented (Hughes-Morley *et al.*, 2015), the recruitment rates experienced in the present study are significantly lower than those found in depression trials conducted with a general mental health population (Richards *et al.*, 2009; Richards *et al.*, 2013). Systematic reviews examining interventions for informal caregivers have also highlighted small sample sizes to be common (Bakas *et al.*, 2014; Brereton *et al.*, 2007; Corry *et al.*, 2015).

Barriers to informal caregivers accessing support potentially explain the poor recruitment rates experienced in this present study (Cameron *et al.*, 2013; Denham *et al.*, 2019a; Denham *et al.*, 2019b). Consistent with barriers to accessing psychological treatment experienced by other populations, informal caregivers view mental health services as predominantly needed for severe psychological difficulties and perceive stigma seeking help and voicing problems (Mosher *et al.*, 2015). Informal caregivers may also view their own needs as secondary to the needs of the person they are caring for and prioritise their caring role over self-care (Carduff *et al.*, 2014; Greenwood and Smith, 2015; Mosher *et al.*, 2015), identifying themselves in terms of the relationship to the person they are caring for rather than as a carer (Carduff *et al.*, 2014; Greenwood *et al.*, 2011). Informal care networks may also be large, with individuals having multiple caregivers (Burns *et al.*, 2013; Koehly *et al.*, 2015). Recruitment focused on the primary caregiver or closest next of kin may therefore miss the opportunity to recruit other network members who provide care.

Given that informal caregivers are also more likely to be late middle-aged and over, it may also be helpful to consider wider barriers to accessing mental health services experienced by an older population (Department of Health, 2009). Evidence suggests that stigma may be a particular challenge in terms of mental health help-seeking among older adults (Hall and Reynolds, 2014; Park and Unützer, 2011) with some older adults considering accessing treatment for depression as a weakness (van der Weele *et al.*, 2012). Additionally, older adults have been found to view depression as an inevitable consequence of ageing, which may also present a barrier to accessing psychological treatment (Law *et al.*, 2010). These attitudes resonate with those held by GPs that may view depression as an inevitable consequence of ageing (Collins and Corna, 2018). It is unsurprising therefore that GPs may normalise the experience of depression as a consequence of the caregiving role and fail to refer older caregivers into IAPT services.

To help address this barrier, the ability to self-refer has been adopted by the IAPT programme (NCCMH, 2019). This approach has been successful in engaging other groups representing diversity, for example in the Newham IAPT pilot site increasing access rates to reflect the ethnic mix of the population previously under-represented by GP referral alone (Clark, 2018).

Further efforts to close the psychological treatment gap (Rebello *et al.*, 2014) have recommended that IAPT services develop closer links with community, third sector and charitable organisations that commonly engage under-represented populations (NCCMH, 2019). Several of these recommendations have been tailored specifically for informal caregivers by the Positive Step IAPT service (North Somerset) with treatment delivery adapted to address common barriers to access (National Health Service England, 2019). This approach to engagement is consistent with previous informal caregiver psychological intervention studies that have recruited successfully by utilising more assertive and collaborative community engagement approaches (Whitebird *et al.*, 2011). IAPT services and future studies may

therefore enhance recruitment rates by engaging more closely with informal caregiver focused community and charitable organisations.

A further important consideration was raised by the severe depression and anxiety scores reported by one informal caregiver at initial assessment and the final treatment session. Consistent with IAPT protocols, a function of weekly case management supervision is to monitor and support decision making regarding high scores and suicidality (Richards, 2010). However, to maintain blinding, individual session data were not provided to the trial team until the end of the trial. This presents an important ethical consideration concerning the design and conduct of pragmatic RCTs carried out in real-world clinical settings. A known difficulty concerning the design and conduct of research in real-world clinical settings is the blurring of boundaries between clinical care and research with respect to role delegation and responsibilities (Nicholls *et al.*, 2019). Within this study, concerns associated with appropriate clinical decision-making for patients reporting consistently high outcomes may have been addressed by establishing an independent Data Monitoring and Ethics Committee to monitor clinical decisions being made. However, there is currently little guidance concerning the ethical design and conduct of pragmatic RCTs (Taljaard *et al.*, 2018).

Conclusion

Substantial feasibility problems highlighted by this study, especially regarding recruitment, indicate that progression to a definitive Phase III (effectiveness) RCT is not feasible at the present time (Craig *et al.*, 2008). However, a greater recognition of barriers to accessing support experienced by informal caregivers alongside enhancing links with community and charitable organisations, may overcome difficulties with recruitment and inform a further Phase II feasibility RCT (Craig *et al.*, 2008).

Limitations

Although the study collected written responses highlighting reasons for non-participation, a thorough qualitative investigation may provide a better understanding regarding the acceptability of the CBT self-help intervention alongside an appreciation regarding barriers to study participation, help-seeking behaviour and barriers to accessing support. Finally, whilst study inclusion criteria did not exclude informal caregivers with moderately-severe to severe depression, recommendations for LICBT is restricted to mild-to-moderate severity (NCCMH, 2019). Including participants with more severe levels of depression may therefore require additional consideration before reaching conclusions about implementing LICBT for informal caregivers of stroke survivors within Step 2 of a stepped care model (Clark, 2018).

Supplementary material. To view supplementary material for this article, please visit <https://doi.org/10.1017/S1754470X20000239>

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Conflicts of interest. Paul Farrand, Joanne Woodford, Chelsea Coumoundouros and Frida Svedin have no conflicts of interest with respect to this publication.

Ethical statements. Authors have abided by the Ethical Principles of Psychologists and Code of Conduct as set out by the APA. The trial was conducted in accordance with Helsinki Declaration to ensure the welfare and rights of the study participants (World Medical Association, 2013). Informed written consent was obtained from all study participants. All data were securely stored and anonymised. The study was ethically approved by National Research Ethics Committee South West for Cornwall and Plymouth (REC reference number: 13/SW/0018).

Key practice points

- (1) Lack of time and poor physical health experienced by informal caregivers should be considered significant barriers to access.
- (2) IAPT services should consider promoting telephone support for CBT self-help as a way to address barriers and improve access for informal caregivers.
- (3) To enhance access, IAPT services should consider greater engagement with informal caregiver focused community and charitable organisations rather than the primary caregivers themselves.
- (4) Given that informal caregivers are likely to be middle-aged and older, it may be helpful to consult the evidence base on overcoming barriers for older people.

Further reading

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