

Internet therapy for dementia caregiver mood

Running header (40/45 characters) Internet therapy for dementia caregiver mood

Title: (98/100 characters) On-line Education and Cognitive Behavior Therapy

improve dementia caregivers' mental health: A randomized trial

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Brief summary (191/200 characters)

A 3-arm RCT of online interventions with 638 dementia caregivers. CBT with telephone support and psychoeducation both improve mental health and mood. Online CBT without telephone support less effective and not recommended.

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Abstract: (296 / 300 words)

Objectives: To compare online Cognitive Behaviour Therapy (CBT) with and without telephone support respectively to online psycho-education in a Randomized Control Trial (RCT) in caregivers of people with dementia with mild anxiety or depression

Design: Three-arm parallel group RCT comparing online CBT with and without telephone support respectively to online psycho-education.

Setting and participants: Online study with caregivers of people with dementia

Measures: The primary outcome measure was mental health measured by General Health Questionnaire (GHQ12) at 26 weeks. Secondary outcomes included the Hospital Anxiety and Depression Scale (HADS); the Relative Stress Scale (RSS) and the Short Sense of Competency Questionnaire (SSCQ). The primary analysis focussed on people completing GHQ12 at both baseline and 26 weeks, evaluated using analysis of covariance.

Results: 638 people were randomized to the 3 treatment arms, of whom 208 were included in the analysis population. There were significant improvements in GHQ12 in all treatment arms compared to baseline ($p < 0.001$ for all interventions), but neither

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CBT with or without telephone support conferred any significant advantage compared to psycho-education. For the secondary outcomes, there were no significant differences between CBT with telephone support and psycho-education, but CBT without telephone support was less effective than psycho-education with respect to HADS depression subscale (mean diff 1.86 95% CI 0.61, 3.11; p 0.004) and caregiver stress (RSS mean diff 3.11 95% CI 0.13, 6.09; p 0.04). Good safety was achieved in all 3 treatment arms, with no deaths or serious adverse events.

Conclusions and Implications: online CBT with telephone support and psycho-education both achieved significant benefits over 26 weeks compared to baseline in mental health and mood, but there were no advantages for CBT compared to the psycho-education intervention. CBT without telephone support was less effective with respect to mood outcomes than psycho-education and should not be recommended based on current evidence.

Introduction

There are 45 million people worldwide with dementia, the majority living in the community supported by family caregivers are enabled to live in their own homes. Caring for people with dementia can create significant stresses ¹ and can have an adverse impact on the mental and physical health ^{2,3}. Support for caregivers is variable ^{4,5} and many individuals face barriers in accessing support ^{6,7}. Full time employment, caring at a distance, competing physical, emotional and practical demands, cost time and travel may all be barriers to accessing face to face services⁸ and more flexible approaches such as online education or therapies may be beneficial.

Psycho-education, caregiver support groups and caregiver training have been evaluated in clinical trials⁹. Meta-analyses and systematic reviews have confirmed that caregiver training, psycho-education and multi-component interventions confer significant but modest benefits ^{10, 11,12}, reducing burden and symptoms of depression ^{13,14}. Multi-component programmes are probably the most effective ^{12,14,15}.

Cognitive Behaviour Therapy (CBT) is a psychological approach that addresses the interaction between people's thoughts, feelings and behaviour and, when delivered in a group, has demonstrated effectiveness for older adults with mixed anxiety and depression ¹⁶. Two studies using the same treatment manual demonstrated benefits for caregivers of people with dementia in modifying unhelpful thinking, improving depression and reducing other mental health symptoms over 8 weekly sessions ^{17,18}. Shorter CBT interventions ^{19- 23} have also shown benefit on symptoms of depression and anxiety.

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Psychoeducation and CBT therefore provide potentially valuable treatments to reduce stress and improve mental health in caregivers, but resources and other barriers have limited widespread implementation.

Internet use has been growing across all age groups²⁴. Delivering appropriately focused support online has the potential to mitigate some of the barriers experienced by caregivers by providing flexibility in location and format, enabling caregivers to engage in therapy at times to suit them.

A systematic review of interventions and a meta-analysis of technology-based approaches including internet-based packages highlighted a small but significant benefit for caregiver burden and depression^{12,25} and may be particularly relevant during the current Covid-19 pandemic. Similar to in-person studies, combined interventions show the strongest effect. However, there are no adequately powered RCTs of online CBT for caregivers of people with dementia. This is an important gap in our knowledge given the established benefits of internet-based CBT (particularly with therapist support) for other conditions^{26,27,28}. Open pilot studies, preliminary work using DVDs and other technology approaches also indicate the need for a larger trial^{29,30,31}.

The aim of the current study was to determine whether online CBT conferred benefits of caregiver mental health. Specifically, our primary hypothesis was that CBT with and without telephone support would confer significantly greater improvement in mental health, measured by the GHQ 12, than psycho-education alone over 26 weeks in caregivers with mild to moderate depression or anxiety. We also hypothesised that for secondary outcomes, compared to psychoeducation, CBT with and without telephone support would confer benefits on mood (anxiety and

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depression measured by HADS), a sense of mastery (measured by SSCQ) and caregiver stress (measured by RSS).

Ethics approval was obtained for the study (REC no. 13/SC/0117).

Methods

Design

Caring for Me and You (CFMAY³²) was a 26-week three-arm randomized controlled trial, comparing online CBT (cCBT) with and without telephone support with a modular online psycho-education intervention all of which were co-produced by caregivers, clinicians and academics and designed specifically for this study. All interventions delivered a 20-session, 20 minutes per session programme which was comparable in overall length to other studies but tailored into manageable individual sessions based on caregiver feedback and these are detailed in Table 1³².

Participant selection and assessment

Participants were aged 18 years or over, family or friends of someone with dementia who self-identified as a caregiver through providing practical and/or emotional support to that person, who may be living with them or in another setting.

Recruitment used a wide variety of sources, including social and print media, the Alzheimer's Society website, posters, information at events and through voluntary sector, NHS and Join Dementia Research³³. Participants registered for the study online via a secure, dedicated website to determine eligibility based on the following inclusion criteria: Living in the UK and experiencing depression of mild/moderate severity (Score of 5-15 on Patient Health Questionnaire PHQ9³⁴ AND/OR anxiety of mild/moderate severity (Score of 5-15 on Generalised Anxiety Disorders Assessment GAD7³⁵). The PHQ9 and GAD7 were used as screening measures and the PHQ9

was also used for safety monitoring. Neither was used as an outcome measure but were chosen for screening to identify those with mild to moderate anxiety or depression using a standard clinical tool used in England's Improving Access to Psychological Therapies Services to enable service benchmarking. The outcome measures described later were selected to provide a general measure of mental health and specific measures of mood, stress and coping comparable with other research studies.

People were excluded if they were receiving psychological therapy from a health professional, receiving treatment from a health professional for use of alcohol or illicit drugs or for symptoms of psychosis. People who scored 2 or 3 on Question 9 of PHQ9 that indicates suicidal ideation were also excluded.

Randomization

Participants meeting the inclusion criteria were randomly allocated in a 1:1:1 ratio to the three treatment arms. This was undertaken using an online computerised randomisation program. The first 10% of participants were randomised using simple block randomisation. A minimisation algorithm (with a random element) was then used to ensure balanced allocation across treatment groups for key prognostic factors: sex, severity of depression (based on PHQ9 scores) and age group.

Interventions

The online interventions were developed collaboratively with caregivers of people with dementia, clinicians and academic experts³². The CBT intervention consisted of 20 x 20-minute sessions that people could access at a time and frequency of their choosing over a period of 26 weeks. The total treatment duration of 400 minutes corresponds well with previous successful treatment packages and the breakdown

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into smaller sessions was led by consumer feedback. The sessions encouraged people to set and review goals and complete activities between sessions. The materials included text and video providing a range of case examples illustrating different caring circumstances, for example, of caregivers of spouses and of parents. Attention was also given to gender and cultural factors for different communities. For example, the video and written materials were varied to illustrate male and female caregivers of different ages and caring relationship and ethnicity, with spoken accents of the video examples reflecting regional differences. Materials were available in an audio and non-audio version.

A package of online psycho-education was designed to match session number and length of the CBT programme. Materials were based on SCIE Social Care Institute for Excellence open Dementia Modules and Alzheimer's Society (England) factsheets to promote understanding about dementia and practical and emotional responses. An overview of sessions is shown in Table 1.

Table 1.

Protocols and training for the telephone support arm of the study were developed based on National Health Service Improving Access to Psychological Therapies (IAPT) protocols, a key service in delivering psychological therapies for people experiencing mild – moderate anxiety or depression in England. Supervision for the telephone support staff, who were graduate psychologists trained in the study protocols, was provided by qualified Clinical Psychologists working in IAPT services.

All the recruitment and interventions took place online, with only the telephone support arm having booked calls with their allocated telephone supporter. A

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Frequently Asked Questions section was available online to help to provide technical support with an option to contact the team if these could not be resolved.

In any treatment or research intervention the needs and mood of participants might vary during the course of their involvement. As the participant screening in this study did not involve a clinician, for safety monitoring, participants in all arms were asked to complete a PHQ9 questionnaire³⁴ each time they logged into the programme. A safety alert was automatically sent to the study team if the participant scored 2 or 3 on PHQ9 question 9 which indicates some suicidal ideation and/or had a total score >19 (a threshold used in IAPT services to identify increasing severity of a person's condition). When alerts were received, the study team followed a protocol mirroring usual IAPT processes. This involved contacting the individual to book a phone call to provide a fuller risk assessment to ascertain their needs, including signposting to further support from their General Practitioner and reviewing whether they should continue study involvement. Serious adverse events and deaths were recorded.

Outcome Measures

Socio-demographic details of age, gender, level of education, relationship to person cared for and time since diagnosis were collected at baseline.

The primary outcome measure was mental health measured by the General Health Questionnaire (GHQ-12)³⁶ rating scale at 26 weeks.

Additional key secondary outcome measures were undertaken at baseline and week 26 and included the Hospital Anxiety and Depression Scale (HADS)³⁷ as a measure of anxiety (HADS-A), depression (HADS-D) and overall mood (HADS total); the Relative Stress Scale (RSS)³⁸ as a measure of stress due to a caring role; the Short Sense of Competency Questionnaire (SSCQ)³⁹ to measure the caregiver's sense of

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mastery/competency in their caring role. Participants also completed a Credibility and Expectancy Questionnaire (CEQ) ⁴⁰ prior to receiving the intervention.

Statistical methods

Baseline characteristics are presented as means with standard deviations for the continuous variables and frequencies with percentages for the categorical ones. The principal comparisons were performed on a modified intention-to-treat basis, including all participants with both baseline and post-baseline assessments for participant reported outcomes. For this trial, the analysis depended on the participants providing data i.e. providing completed questionnaires irrespective of whether they completed any of/all the training sessions. The primary and secondary outcomes were analysed using analysis of covariance (ANCOVA). All non-missing responses were included in the model. The model included the post-baseline outcome score as the response variable with randomised group, stratification factors and baseline outcome score as the explanatory variables. Results are presented as differences in means with 95% confidence intervals or standard deviations, with no adjustment for multiple comparisons. Treatment comparisons are presented for arm 1 vs arm 3 and arm 2 vs arm 3. The study was not powered to compare the two CBT arms (arm 1 vs arm 2). A further exploratory analysis was undertaken to compare baseline scores with week 26 scores for each outcome measure in each of the treatment arms using the paired sample t-test.

Analysis were undertaken using Stata version 15.0 and 15.1 (StataCorp, College Station, TX).

Trial registration. ISRCTN41346609

Results

Participant flow

1,122 people expressed an interest in the study and completed an initial screening. Of these, 484 did not meet eligibility criteria and the remaining 638 (57%) were randomised to the three study conditions as shown in the CONSORT chart Figure 1 (see Appendix 1)

Participant characteristics

There were no statistical differences between the arms in terms of socio demographic and clinical characteristics shown in Table 2.

Table 2.

The age range of participants was 18-101years with more than half of participants of working age (under 65 years) and a median period of time as a caregiver of 1-3 years. Participants registered from geographical areas across the UK.

Treatment acceptability

Overall, 26% of randomised participants completed 80% or more of the sessions, with 46% completing at least one session. The score on the CEQ of credibility and expectancy of treatment did not predict the number of sessions participants completed. Of the 54% of people who did not complete a session, 20% were in the unsupported cCBT arm, 11% in cCBT with telephone support and 23% in psychoeducation arm. Completion rates are consistent with previous internet delivered studies.

Main findings

There were no significant differences in the GHQ-12 (primary outcome measure) at 26 weeks between the CBT arms with and without telephone support respectively and psycho-education. For the secondary outcome measures (HADS total score, HADS -D, HADS-A, RSS, SSCQ), similarly, there were no statistically significant differences between CBT with telephone support and psychoeducation. However, at 26 weeks CBT without telephone support conferred significantly less benefit than psycho-education for mood (HADS-T) (mean difference 2.64, 95%CI 0.29-5.0 $p=0.028$), depression (HADS-D) (mean difference 1.865, 95% CI 0.611,3.11, $p=0.004$) and caregiver stress (RSS) (mean difference 3.11, 95% CI 0.13,6.09 $p=0.04$). The full results for the between group comparisons are shown in table 3.

Table 3

Exploratory Analyses

Table 4 presents an exploratory analysis showing the mean score change between baseline and 26 weeks in each treatment arm for the different questionnaires. The standard deviation is also presented, along with the resulting t-test, two sided p-value. There was a ~3-5 point improvement on GHQ-12 scores in each treatment arm, which was statistically significant.

There was a statistically significant improvement on all the measures from baseline to 26 weeks in the telephone supported cCBT treatment arm. In the psycho-education arm there were significant improvements from baseline on the HADS-depression scale and sense of competency (SSCQ), but not on the total HADS score or Relative Stress Scale (RSS). Except for the GHQ-12, there were no

significant improvements on the other outcome measures in the group receiving CBT without telephone support.

Table 4

Safety

There were no serious adverse events and no deaths. Session by session safety monitoring of the total of 3,611 times participants logged in to start sessions created 46 safety alerts, based on pre-specified PHQ-9 questionnaire thresholds were related to 35 individuals. No individuals were withdrawn from the study because of safety alerts.

Discussion

CFMAY, the first well powered RCT of online CBT for caregivers of people with dementia, has demonstrated that it is safe and feasible to deliver online psycho-education and CBT programmes to a geographically, demographically and clinically diverse range of caregivers with mild to moderate anxiety and/or depression, including caregivers of working age who may find it difficult to access traditional caregiver support groups. The age range of participants was 18-101 years, with a mean age of 60 years, demonstrating that online approaches are appealing to a wide cohort of individuals, who were predominantly spouses or children of people with dementia. However further work to improve engagement is important and understanding people's needs within this heterogeneity may be helpful. CBT with telephone support conferred significant benefits on all measures compared to baseline, with psycho-education showing benefits for mental health, depression and sense of competence compared to baseline. Of note, online CBT without telephone

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support led to significantly less improvement for depression and stress than psycho-education and is not recommended as an intervention approach for caregivers of people with dementia.

A meta-analysis of previous studies focussing on internet delivery of interventions for dementia caregivers, with or without telephone support, highlighted favourable outcomes for psycho-education, particularly as part of multi-component interventions¹². The current study supports the value of psycho-education for dementia caregivers, with significant benefits in mental health, mood and sense of competency. The challenge of caregiving involves practical everyday issues ranging from hands on health and personal care, accessing appropriate resources and support to managing specific interactions with a person with dementia as well as psychological and emotional elements. This breadth of practical and psychological challenges may explain why multi-component interventions have emerged as particularly beneficial from previous studies. In the current study, online CBT with telephone support did not confer advantages compared to psycho-education, and therefore we do not feel it can be preferentially recommended as a first line intervention for caregivers with mild anxiety or depression.

It should be noted however, that the participants were volunteers and not a clinical population, and that the needs of individuals in contact with clinical services, or with more severe mood disorder or stress may be different. Online CBT with telephone support needs to be evaluated further in these groups. CBT without telephone support was significantly less beneficial than psycho-education on several key measures of mood and based on current evidence we would caution against the use of online CBT without telephone support outside the context of research studies.

It is important to understand the current results in the context of individualised in-person CBT based approaches. The closest study for comparison is START ²¹ a 'coping'-focussed intervention encompassing psychoeducation, relaxation, pleasant event scheduling, thought challenge, behavioural management and communication strategies. START was compared to treatment as usual (TAU) in a 2 arm RCT with 260 participants. At 12 months for the TAU group there was no change in HADS total score, with a slight subsequent worsening at 24 months. In comparison the START group improved by 1 point on the HADS-T scale at 12 months but returned to baseline levels at month 24. The START intervention did demonstrate significant advantage in comparison to TAU. In the CFMAY study at 26 weeks there were improvements on HADS total score compared to baseline of 2.4 points in the psycho-education arm and an improvement of 3.36 points in the group receiving online CBT with telephone support. Whilst it is difficult to compare studies due to differences in population and design, the benefit from baseline in the current study appears to be more substantial than that achieved in the START intervention programme. We would suggest that a further RCT of an in-person CBT based intervention is needed with an active control in order to better understand the relative merits of psycho-education and CBT.

The packages we developed were co-produced with caregivers of people with dementia ³² and aimed to be shorter than traditional packages to encourage engagement. These 20-minute sessions also seemed to be in line with evidence that the average amount of time spent on website is 18 minutes ⁴¹. However, this did not appear to impact on adherence to the study as our findings were similar to other studies ⁴². Importantly, the telephone supported arm of cCBT achieved higher levels of engagement, with almost twice as many participants completing the outcomes at

26 weeks compared to the unsupported arms. This is consistent with previous reviews of the literature^{43,26}. For future work, telephone support for psycho-education packages and options for personalised support should be considered and may improve engagement. Further work on the benefits for telephone supported online CBT with those who have not benefitted from psychoeducation or those with severe clinical need is also indicated.

Safety is often an overlooked element of online interventions, and we felt this was an important component of delivering an intervention to individuals with symptoms of anxiety and depression. There were no deaths or serious adverse events amongst participants. The automated process of pre-specified flags for individuals' sessional worsening mood or suicidal ideation worked well. It enabled provision of appropriate support and we believe is an important part of safely delivering online therapies to potentially vulnerable individuals and avoiding the occurrence of any serious adverse events.

The high drop-out rate should be acknowledged as a limitation, although it is consistent with other studies of online therapies⁴². Unfortunately, we were not able to follow up people who did not complete the study to gain some insight into their reasons for this. The main other limitation of the study was the absence of measurement of factors related to the severity and characteristics of dementia amongst people being cared for. Although the demographic factors included the length of time the person had been caring, other studies have shown that there are multidimensional determinants of caregiver sense of burden and distress including, for example, the more advanced stages of disease progression which are

significantly associated with higher scores of caregiver burden ⁴⁴. In addition, rapid changes in technology and adoption of smart and mobile technology has been evident ⁴⁵, and there would now be opportunities to further evolve the delivery of the intervention. Given the heterogeneity of our participants in terms of age and their relationships to the person and the length of time they had been providing support, it may be helpful to create further bespoke optional sessions within the programme. Sessions that address both the immediate post-diagnostic, the long term and changing nature of caregiving could further personalise the approach. Modules specifically relevant to the challenges for caregivers when a person with dementia moves into a residential care or nursing home setting and more direct information regarding services and financial support may address caregivers' changing needs.

Conclusion and Implications

Online psycho-education is a helpful approach for supporting caregivers experiencing mild-moderate levels of anxiety and/or depression and should be more widely available. Telephone supported cCBT conferred similar benefits and had greater levels of adherence but has greater resource implications. The use of CBT without telephone support was less effective than psycho-education and should not be recommended for caregivers of people with dementia.

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Tables and Figures (5/5)

Table 1. Session content for the CBT and on-line education arms

20-minute sessions	Computerised CBT	Online Education *
Session 1	Introduction: Being a caregiver	Introduction
Session 2	Understanding Dementia	What dementia is and what it isn't
Session 3	Understanding yourself and your reactions	Living with dementia
Session 4	Understanding more about yourself	What causes dementia?
Session 5	How you think affects how you feel	Diagnosis and who can help (double-length Session)
Session 6	Thinking about things differently (emotion 1)*	Diagnosis and who can help
Session 7	Checking out your thoughts (emotion 1)*	Common difficulties and how to cope
Session 8	Thinking about things differently (emotion 2)*	The emotional impact of dementia
Session 9	Checking out your thoughts (emotion 2)*	Positive communication (double-length Session)
Session 10	Thinking about things differently (emotion 3)*	Positive Communication
Session 11	Checking out your thoughts (emotion 3)*	Planning ahead
Session 12	Thinking about things differently (emotion 4)*	Safety and comfort at home
Session 13	Checking out your thoughts (emotion 4)*	Personal care
Session 14	Understanding someone with dementia's needs	Staying healthy
Session 15	Ways to respond to stress	Maintaining wellbeing
Session 16	How your thinking can affect your interactions	Changes in behaviour
Session 17	Being kind to yourself	Treatments
Session 18	Coping with setbacks	Selecting a care home
Session 19	Creating a blueprint	Taking a break
Session 20	Continuing your journey	Looking after yourself

*Sessions 6-13 of the CBT arms used a CBT framework for recognising and coping with four common emotions (identified by caregivers as most relevant during the co-

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produced development phase). These four emotions were anxiety, depression, anger and guilt. Participants chose the order in which they worked through the sessions by rating their experience of the four common emotions. The most pertinent to their situation being delivered first. This interactive element of the programme enabled a personalised approach

Table 2. Baseline Characteristics of intention to treat population

Baseline characteristics by Arm				
Variable at baseline	cCBT (n=213)	cCBT + telephone support (n=213)	Online Education (n=212)	Total (n=638)
Age, Mean (SD)	60.2 (12.1)	60.2 (12.6)	59.2 (12)	59.9 (12.2)
Gender (Female)	182 (85%)	182 (85%)	181 (85%)	545 (85%)
Education				
School level	54 (25%)	37 (17%)	48 (23%)	139 (22%)
College/Sixth form	60 (28%)	71 (33%)	60 (28%)	191 (30%)
Further education	99 (46%)	105 (49%)	104 (49%)	308 (48%)
Relationship to person with dementia				
Partner	91 (43%)	102 (48%)	85 (40%)	278 (44%)
Child	76 (36%)	77 (36%)	82 (39%)	235 (37%)
Other	46 (21%)	34 (16%)	45 (21%)	125 (19%)
When patient diagnosed				
< year	25 (12%)	26 (12%)	32 (15%)	83 (13%)
1-3 years	100 (47%)	97 (46%)	104 (49%)	301 (47%)
4-5 years	45 (21%)	56 (26%)	40 (19%)	141 (22%)
6-10 years	29 (14%)	25 (12%)	23 (11%)	77 (12%)
>10 years	14 (7%)	9 (4%)	13 (6%)	36 (6%)
Scores				
GHQ-12	16.34 (4.05)	16.27 (4.06)	16.45 (3.93)	
HADS - Total score	17.13(6)	16.52(5.510)	16.41(5.40)	
HADS - Anxiety score	9.54 (3)	8.95 (3.29)	8.92 (3.11)	
HADS -Depression score	7.58 (4)	7.56 (3.5)	7.5 (3.55)	
RSS	28.6 (7.95)	29.2 (8.33)	28.4 (8.28)	

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SSCQ	15.56 (5.15)	14.96 (4.52)	15.78 (5.34)	
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GHQ-12 = General Health Questionnaire 12 item version, HADS = Hospital Anxiety and Depression Scale, RSS = Relative Stress Scale, SSCQ = Short Sense of Competency Questionnaire

Table 3. Primary and Secondary Outcome Comparisons between cCBT with and without telephone support and psychoeducation at 26 weeks

Variables	cCBT vs Psychoeducation			cCBT +Telephone support vs Psychoeducation		
	Mean diff	95% CI	p	Mean diff	95% CI	p
GHQ-12	1.07	0.9,1.28	0.43	0.87	0.75,1.02	0.09
HADS -Total	2.64	0.29, 5.0	0.028	-1.47	-3.48,0.55	0.15
HADS-Anxiety	0.84	-0.49, 2.16	0.22	-0.99	-2.12,0.14	0.09
HADS-Depression	1.86	0.61, 3.11	0.004	-0.47	-1.55,0.60	0.39
RSS	3.11	0.13,6.09	0.04	-1.44	-4.01,1.13	0.27
SSCQ	-0.93	-2.49,0.64	0.24	0.34	-1.01,1.69	0.62

GHQ-12 = General Health Questionnaire 12 item version, HADS = Hospital Anxiety and Depression Scale, RSS = Relative Stress Scale, SSCQ = Short Sense of Competency Questionnaire

For GHQ-12, HADS and RSS positive scores indicate relative worsening and negative score indicate relative improvement.

For SSCQ positive scores indicate relative benefit and negative score indicate relative decline.

Table 4. Comparison of change in outcome measures between baseline and week 26 *

	Mean Diff. (SD), P-value		
	cCBT at 26 weeks (n=53)	cCBT + telephone support at 26 weeks (n=101)	Online education at 26 weeks (n=54)
GHQ12	-2.69 (5.73), 0.001	-4.83 (6.43), <0.001	-4.26 (5.18), <0.001
HADS Total	0.82 (6.76), 0.388	-3.11 (6.64), <0.001	-1.17 (4.68), 0.073
HADS – Anxiety	0.020 (3.71), 0.970	-1.57 (3.86), <0.001	-0.33 (2.94), 0.408
HADS – Depression	0.80 (3.79), 0.137	-1.54 (3.36), <0.001	-0.83 (2.68), 0.026
RSS	0.90 (8.46), 0.450	-3.63 (8.24), <0.001	-1.57 (6.39), 0.076
SSCQ	0.45 (4.44), 0.472	1.99 (4.33), <0.001	1.33 (3.87), 0.014

GHQ-12 = General Health Questionnaire 12 item version, HADS = Hospital Anxiety and Depression Scale, RSS = Relative Stress Scale, SSCQ = Short Sense of Competency Questionnaire

For GHQ-12, HADS, RSS a negative score indicates an improvement from baseline to week 26 and a positive score indicates a worsening from baseline to week 26. For SSCQ a positive score indicates an improvement from baseline to 26 weeks.