A randomised controlled trial of a community based group guided self-help intervention for low mood and stress.

Christopher Williams[1] (MD), Carrie-Anne McClay (BA, Hons) [1], Lynsay Matthews [1] (PhD) Alex McConnachie[2] (PhD), Caroline Haig[2] (PhD), Andrew Walker[2] (PhD), Jill Morrison[3] (PhD)

1. Institute of Health and Wellbeing, University of Glasgow, Gartnavel Royal Hospital, Administration Building, 1055 Great Western Road, Glasgow, Glasgow City G12 0XH.

2. Robertson Centre for Biostatistics, Boyd Orr Building, University of Glasgow, Glasgow, G12 8QQ

3. General Practice and Primary Care, Institute of Health and Wellbeing, University of Glasgow, 1 Horselethill Road, Glasgow, G12 9LX

Correspondence to:

Professor Christopher Williams

Institute of Health and Wellbeing
University of Glasgow
Institute of Health & Wellbeing
1st Floor Admin Building
Gartnavel Royal Hospital
1055 Great Western Road
Glasgow G12 0XH

Tel. 0141 211 3912

Fax. 0141 211 3889

Email: chris.williams@glasgow.ac.uk

Abstract

Trial design: A pre-post RCT of an 8-week class-based life-skills course with a delayed access control group for anxiety and depression.

Methods: This study aimed to assess the effectiveness of community-based cognitive behavioural therapy (CBT) self-help group classes on symptoms of depression, anxiety and social function at 6-months. 142 participants were randomly allocated to immediate (n=71) or delayed access to the low intensity CBT intervention (n=71). Measures of depression, anxiety and social function were collected at baseline and 6-months. No studies have explored the effectiveness of written CBT resources for low mood and stress delivered via a course of self-help classes in a community setting.

Results: A significant improvement was observed for the primary outcome of PHQ-9 score (mean between-group difference: -3.64; 95% CI -6.06, -1.23; p=0.004). The percentage of participants reducing their PHQ9 score between baseline and 6 months by 50% or more was 17.9% (Delayed Access - DA), and 43.8% (Immediate Access - IA). The percentage of participants reducing their PHQ9 score by 5 or more points was 30.4% (DA) versus 56.2% (IA). Secondary outcomes also improved including anxiety (GAD-7 score -2.83; 95% CI -5.03, -0.64, p=0.012) and social function (WSAS -5.31; 95% CI -9.35, -1.27, p=0.011). Additional measures of depression and anxiety (HADS) also significantly improved at 6-months in the IA group compared to DA. The intervention was cost neutral. The probabilities of a net benefit at willingness to pay thresholds of £20,000, £25,000 or £30,000 were 0.928, 0.944 and 0.955 respectively.

Conclusions: Low-intensity class-based CBT classes delivered within a community setting are effective for reducing depression, anxiety and impaired social function at little additional cost.

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Keywords

Depression, CBT, guided self-help, groups, RCT, economic analysis, bibliotherapy, anxiety.

BACKGROUND

Depression and anxiety, place a significant burden on health services. In 2011/2012 the cost of prescribed antidepressant medication in Scotland was £31.4 million.[1] Mood disorders were also the most prevalent psychiatric hospital discharge diagnosis in women in Scotland in 2012.[2] Depression can be treated effectively within primary care.[3] However, fewer than 50% of patients receive treatment.[4] This *treatment gap* may be due to non-presentation for fear of stigma or uncertainty of treatment options.[4] A community setting, where voluntary organisations and self-help groups provide local support networks, may be more appealing.[5] Interventions which undertake community-based promotion, recruitment and delivery, may therefore have the potential to engage people who would otherwise not present to the health service.

The National Institute for Health and Care Excellence (NICE) recommends Cognitive Behavioural Therapy (CBT) as a treatment option for mild to moderate depression.[6] High intensity forms of CBT delivered by a mental health expert are recommended to treat moderate and severe levels of depression [7]. This approach is therapist-intensive and access for patients can be limited due to long waiting lists.[6] Consequently, delivery systems are changing, for example with increasing proportions of patients offered low intensity delivery as a first step in the Increasing Access to Psychological Therapies (IAPT) program in England. *Low intensity* forms of CBT include written self-help books, computerised CBT and self-help groups.[8-11] Although less therapist-intensive, individual support is still provided via phone or face-to-face by workers such as self-help coaches or psychological wellbeing practitioners.[12]

A limited number of low-intensity community interventions have been previously assessed in RCTs. Previous studies either assessed the effect of a single one-off class,[13] or focussed on stress/anxiety.[14] NICE found no low-intensity CBT classes addressing depression and also associated health economic outcomes.[6] This study attempts to address the research gap by being the first intervention to explore low-intensity CBT classes for low mood and stress guided by self-help resources delivered in a community setting.

The Living Life to the Full Classes

The Living Life to the Full (LLTTF) classes[15] consist of eight, weekly, 1.5 hour sessions in a classroom where participants with depression and anxiety are guided through a CBT-based life-skills course by trained class leaders. A pilot RCT[16] demonstrated effective recruitment and adherence, and found improved levels of anxiety and depression 3-months after randomisation.

Aims

To compare the effectiveness of a community-based CBT self-help group intervention in improving symptoms of depression, anxiety and social function at 6-months.

The research questions of the study are as follows:

Primary question:

Does immediate access (IA) to the LLTTF classes result in an improvement in symptoms of depression at 6 months compared to a delayed access control (DA) group?

Secondary questions:

a.) Does immediate access to the LLTTF classes result in an improvement in anxiety and social function at 6 months, compared to DA.

b.) Is the intervention cost effective?

c.) Is the intervention satisfactory to participants?

METHODS

Study design and participants

The study used an individually randomised design with delayed access control. Community recruitment methods included newspaper advertisements and assistance from the Scottish depression charity Action on Depression. A series of Metro (free newspaper) adverts were placed during two, six week recruitment periods between August 2012 and February 2013 (4 adverts per week plus online advertising and occasional feature sized making up approximately quarter of a page in the classified advertisement area of the paper). Adverts included the following text *"Living life to the full Living life to the Full Project, I can't be bothered. What's the point? I don't enjoy doing that anymore. I am fed up. Does this sound like you? If so, you may be suffering from low mood. These are very common problems and with help, can be greatly improved. If you would like to attend relaxed, friendly, local life skills classes that aim to help you get your spark back, contact (name) on*

(phone no.), complete the eligibility and consent forms attached or email (university email address). We provide the tea and biscuits!"

Action on Depression advertised the study via their website, phone support line, newsletters and local groups. Participants included individuals who were, and were not, currently receiving NHS help for their symptoms of depression and anxiety throughout Central Scotland. Data was collected and stored at the University of Glasgow. The study commenced in July 2012, recruitment began in August 2012 with the final data analysis being completed in January 2014.

Inclusion criteria: Aged 16 years of age or older with at least mild depressive symptoms, defined as a score ≥5 on the Patient Health Questionnaire-9 (PHQ-9).[17]

Exclusion criteria: Currently receiving psychotherapy/talking therapy or counselling; unable to read, speak or understand English; unable to travel to classes; no consent to abide by normal social etiquette within the classes. With the aim of being inclusive in this community based trial, we minimised exclusion criteria. No upper cut-off for depression score was used in line with our previous work. This approach was successfully employed in the pilot study[16] and suited the inclusive pragmatic delivery using voluntary sector staff. This approach is unusual in low intensity settings, however is in line with NICE low intensity guidelines which emphasise complexity rather than severity of depression alone[6].

Online studies have sometimes been criticised because of a concern that participants may not satisfy the criteria for clinical depression[18] and therefore do not reflect the sorts of people attending clinical services. Participants were therefore asked to complete a MINI international psychiatric diagnostic interview (Version 6.0)[19] via telephone with a research assistant (RA to better describe the recruited sample in terms of their past, present or recurring depression

Randomisation

When sufficient participants to fill at least two classes had undergone baseline assessments, the statistician performing the randomisation was sent a file containing study ID, plus the minimisation factors of preferred time (afternoon or evening) and location (Glasgow or Edinburgh) of class, and PHQ9 score (<=9, >=10). No other information (e.g. age, sex) was included.

A computer program was then written to randomly assign individuals to the immediate or delayed intervention groups in equal numbers (or as close as possible, if there was an odd number of

individuals being assigned). After assigning all individuals, the program checked whether the treatment balance for each time/location subgroup, and for each PHQ9 subgroup, was as close to equal as possible (i.e. equal, or out by one). If not, the process was started again, and repeated until an assignment was reached which resulted in minimal imbalance between treatment groups in relation to each minimisation factor.

This was first carried out in October 2012, once the first wave of participants had completed their baseline assessments. In March 2013, a second wave of participants was recruited. The above process was repeated, with the modification that when a random allocation of this second wave was attempted, the treatment group imbalance was assessed in relation to all study participants (including those randomised in October 2012), in order that the final study treatment groups were well balanced in relation to the minimisation factors over the entire study population.

All computer programs and treatment allocation files were stored in a restricted area of the Robertson Centre for Biostatistics (RCB) network, with access only for the study statisticians. Analyses were carried out by junior staff in accordance with the study protocol, and results were reviewed by senior statistical and health economic staff prior to dissemination. The IA group began attending classes within 2-3 weeks of randomisation. The DA group were advised to continue usual management of their symptoms and began attending classes after a delay of 6-months.

Blinding:

The Robertson Centre for Biostatistics (RCB), where the analyses were carried out, is part of the UKCRC-registered Glasgow Clinical Trials Unit. For regulatory clinical trials and other major randomised studies, treatment group allocations are routinely masked from the statisticians, until database lock. This study was an academic trial with a small budget, so could not be carried out with the same level of restrictions. The statistician carrying out the analysis had access to randomisation codes throughout the analysis. Nevertheless, the analyses were carried out in accordance with the statistical section of the study protocol and the original funding application, which were written prior to the trial.

The researchers were necessarily unblinded, since they had to arrange the LLTTF classes with study participants. Randomisation took place in two blocks, with the first 104 participants randomised in October 2012, and the remaining 38 randomised in March 2013. On each occasion, all baseline data was collected prior to randomisation being carried out, ensuring that neither participants nor

researchers could anticipate which group an individual would be assigned to at the point of baseline data collection. At follow-up, data was collected via online participant self-completed questionnaires, without direct contact with study researchers. The final study database, with randomised group allocations, was provided to the study statistician for analysis, which was carried out according to the plan specified in the study protocol paper.

Intervention: The Living Life to the Full classes

LLTTF classes were delivered by the charitable organisation *Action on Depression* (AOD) and involved eight, weekly classes that taught a range of CBT-based life skills. Classes were 90-minutes long, attended by up to 16 participants and were conducted in a classroom setting based in a locally accessible location e.g. library. Two experienced, trained class leaders from AOD, used pre-prepared locked slides and support notes/scripts. Trainers were all AOD volunteers from varying backgrounds including general public, psychology assistant, a nurse, and AOD staff members. All had experience of mental health presentations and support, and in each training pair at least one was an experienced facilitator who had delivered the classes before.

Each weekly class focused on a different common problem faced by people when they feel low or anxious with content produced by a trained and qualified CBT practitioner and covering key CBT content[6,9,16]. The class content is: *1: Why do I feel so bad? (self-formulation/CBT model), 2: I can't be bothered doing anything (behavioural activation), 3. Why does everything always go wrong? (identifying and changing negative automatic thoughts), 4: I'm not good enough: (low confidence), 5: How to fix almost everything (problem solving strategies), 6: The things you do that mess you up (reducing safety behaviours), 7: Are you strong enough to keep your temper? (anger and irritability)* and *8: 10 things you can do to help you feel happier straight away (healthy living, a reminder of core principles in the course).* A ninth session, Planning for the Future and Reunion addressing relapse prevention, is held 6 weeks after the final class. As seen in the session names, the classes use everyday language and avoid professional terminology in order to make the intervention accessible to all whilst covering key CBT topics such as altered thinking, behavioural activation, problem solving and relapse prevention. This way of communicating CBT is highly accessible[20] and shown to be helpful in previous trials[21,22]. They are designed to encourage an individualised plan to be made at the end of each session using a Plan, Do, Review structure[23] here are currently no equivalent classes using the same model of delivery.

Fidelity of class delivery was assessed by the lead research assistant and an independent research volunteer. Two consistency checks per 8-week course were carried out using a consistency check-list for adherence to class content and quality of delivery.

The Living Life to the Full (LLTTF) classes contain eight life skills sessions that teach a range of CBT-based life skills in a classroom setting based in a locally accessible location such as a library or hotel. Classes are attended by up to 16 people and last 90 minutes.

Measures

The primary outcome was level of depression at 6 months assessed by the PHQ-9. Secondary measures included the Generalised Anxiety Disorder Scale (GAD-7)[24], Hospital Anxiety and Depression Scale (HADS)[25] and the Work and Social Adjustment Scale (WSAS)[26]. In addition, satisfaction was recorded using the client satisfaction questionnaire (CSQ-8)[27]. The CSQ-8 is an 8 item questionnaire rated using a 4 point Likert scale. Scores range from 8-32 with higher scores indicating greater satisfaction with the intervention in question.

Statistical Methods

Outcome measures were compared between study groups on an intention to treat basis using linear regression models adjusting for baseline values of the outcome and age, sex, duration of symptoms, use of antidepressants and randomisation stratification variables (time/location of class, PHQ-9 ≤9/≥10 at baseline). We also reported the primary outcome in terms of the proportion of participants scoring 9 or less on the PHQ9 (reflecting mild depression), the number of people dropping 5 points or more on the PHQ9 (reflecting category improvement and is seen as an "adequate" improvement), and the proportion of participants whose PHQ9 score dropped by 50% or more between baseline and 6 months (as widely used in IAPT and many clinical services). Subgroup analyses were carried out to test for interactions between study group and baseline PHQ-9 (≤9/≥10), age, gender, duration of symptoms and antidepressant use at baseline. All analyses were carried out using R for Windows 3.0.2[28]. P-values <0.05 were considered statistically significant.

Statistical power and sample size

A criticism made of studies using self-referral and community-based recruitment is that participants are not significantly depressed. We therefore powered the study to detect a clinically significant difference of 5.5 points[29] on the PHQ-9 within the subgroup of participants with more severe depression (PHQ-9≥10) at baseline.

Our pilot study[16] showed that for those with a PHQ-9≥10 at baseline, the standard deviation of changes in PHQ-9 scores was 6.1. Based on a two-sample t-test, a sample size of 54 participants would be required for 90% power. In the pilot, follow-up data was available for 65% of participants, so we needed to randomise 84 participants with PHQ-9 scores ≥10. We expected one third of participants to have PHQ-9<10 at baseline, so we aimed to randomise 126 participants in total.

Our trial design has been reported in a protocol publication.[30]

Economic analysis

Economic analysis was performed from a health service perspective as recommended by NICE.[31] The Client Service Receipt Inventory (CSRI)[32] and EQ5D[33] were used to measure participants' use of health services and current state of health. Health service costs were calculated from self-report in the CSRI over 6 months. The costs used were obtained from Unit Costs of Health and Social Care (2015). Generalised linear models with the log link function were applied to model costs and QALYs in relation to study group. The method of recycled predictions was used to estimate the differences in costs and QALYs between randomised groups, using 10,000 bootstrapped datasets, stratified by randomised group. These estimates were plotted on the cost-effectiveness (CE) plane. Interpretation was aided using cost-effectiveness acceptability curves derived using the net-benefit approach with values between £0 and £100,000 placed on a QALY gain to include the threshold used by NICE.[34]

Ethical Approval and trial registration

Ethical approval was granted by the College of Medical, Veterinary & Life Sciences Ethics Committee for Non Clinical Research Involving Human Subjects, University of Glasgow, Ref. 2012065 and in line with the Declaration of Helsinki. The study is registered with Current Controlled Trials, Ref: ISRCTN86292664.

RESULTS

Participant characteristics

Figure 1 presents a CONSORT diagram. The required number of participants scoring 10+ on the PHQ-9 entered the study before ending recruitment. Demographic data at randomisation are presented in Table 1. Baseline measures are presented in Table 2. At 6-months 71.8% (n=102 of 142) were followed up. No noticeable differences in demographic data were found between the IA and DA groups at baseline, or in rates of drop-out at 6 months. There were also no significant differences in age (p=0.97), gender (p=0.63), chronicity (p=0.33) or PHQ severity at eligibility (p=0.21) between completers and non-completers (those providing 6 month follow-up data vs drop-outs). All measures (apart from the MINI) were completed at baseline and 6 months in order to maximise response rate at the primary outcome (6 months) and to avoid participant burden with repeated questionnaires. No further measures were taken after the delayed group received their intervention, a requirement of the funders

Main Outcomes

The percentage of participants reducing their PHQ9 score between baseline and 6 months by 50% or more was 17.9 (DA), and 43.8 (IA) (P=0.008). The percentage of participants reducing their PHQ9 score by 5 or more points (representing a clinically meaningful shift in severity category) was 30.4% (DA) versus 56.2% (IA) (P=0.014). The percentage of participants scoring 9 or lower at follow-up was 62.5% (IA) compared to 32.1% (DA) (P=0.004); at baseline this was 17.5% and 15.4 for IA and DA, respectively (P=0.938).

Table 3 and Figure 2 present further outcome measures for PHQ-9, GAD-7, HADS-D, HADS-A and WSAS at baseline and 6-month follow-up. A significant difference in favour of the IA group was observed for PHQ-9 (-3.64; 95% CI -6.06, -1.23; p=0.004) and GAD-7 (-2.83; 95%CI -5.03, -0.64, p=0.012). Additional measures of depression and anxiety (HADS) also significantly improved at 6-months in the IA group compared to DA. Social function as measured by WSAS at 6-months was improved in favour of the IA group (-5.31; 95% CI -9.35, -1.27, p=0.011).

A significant treatment effect was observed for participants with a baseline PHQ-9 ≥10 (n=86) (-5.37; 95%CI -8.33, -2.42, p<0.001), whereas those with baseline PHQ-9 ≤9 (n=18) showed no change at follow-up (1.15; 95%CI -3.33, 5.62, p=0.591) (p-value for interaction, 0.045). No significant interactions were observed with respect to age, gender, duration of symptoms or

antidepressant use at baseline. In relation to deterioration, defined as any increase in PHQ-9 score at 6 months compared to baseline, the difference between groups did not reach statistical significance ($p = 0.07$). However, there is a trend towards greater deterioration in the DA group as in the immediate access group, 8 of 48 deteriorated (16.7%) whilst 19 of 56 (33.9%) in the delayed access group showed an increase in PHQ-9 score at the follow-up point. It is possible that the study is not adequately powered for the deterioration analysis.

Cost-effectiveness: Total NHS treatment costs in the 6-months prior to LLTTF were £907 and £802 for the IA and DA group, respectively, and reduced during the 6-month intervention to £780 and £740, respectively. The probabilities of a net benefit at willingness to pay thresholds of £20,000, £25,000 or £30,000 was 0.928, 0.944 and 0.955 respectively (Figure 3). The net result was improved outcomes and high satisfaction in the intervention group at a similar cost to not delivering the classes (Figure 4).

Given that the classes have a fixed cost, then if the intervention has no effect on health service utilisation, we would expect there to be a difference in cost between the intervention and control groups. In order to estimate the mean difference in costs between groups, we fitted a regression model. For this model to be valid, we must adjust for the stratification variables (location/time and baseline PHQ-9 category), regardless of their significance in the model.

The p-value of 0.998 for the intervention effect estimate means that there is no evidence of a difference in the mean cost between the two groups. The point estimate for the intervention effect is close to null, suggesting that the cost of the intervention may be offset by a reduction in health service utilisation. However, the confidence interval for the relative cost difference is wide (roughly 60% either way), and from the recycled predictions, the confidence interval for the difference in mean costs between groups is approximately -£400 to +£500; these both indicate a high degree of uncertainty. Similarly, there is no evidence of a difference in QALYs between groups, but in this case the trend is towards a benefit in the intervention group.

Taken together, these data suggest that the intervention may be resulting in a reduction in health service utilisation and an improvement in quality of life, which would be consistent with the improvements in symptoms observed in the study. However, probably due to the high variability in these measures, we cannot estimate the between group differences with very much precision. In order to obtain definitive answers in terms of the cost effectiveness of the intervention, we suggest

that further research is required, with a larger sample size, in order to narrow these confidence intervals.

Attendance, Participant Satisfaction and Protocol Fidelity: In the IA group 35.2% (n=25 of 71) failed to attend classes and dropped out of the research study. Reasons for drop-out included: alternative treatment (n=5); lack of time (n=4); deteriorating mood (n=3); moved house (n=1); and no reason given (n=12). Of the remaining participants, 93.5% (n=43) attended at least one of the LLTTF classes. 78.3% (n=36) attended ≥4 sessions, with 34.8% (n=16) attending all 8 sessions (Figure 5). Mean participant satisfaction with the LLTTF classes (IA group) was high with a CSQ-8[27] score of 24.3 (sd 5.1) (n=47). Participant satisfaction with the classes increased as their symptoms of depression, anxiety and social function improved. Classes were rated as useful, quite useful or extremely useful by 81.8% of IA participants who returned class feedback forms (n=36 of 44). Seventeen LLTTF classes were monitored for protocol fidelity. All sessions were rated as competently delivered with a mean consistency checklist score of 8.8 (sd 1.1) and a mean class leader presentation score of 9.6 (sd 1.1) from a maximum score of 10.

Discussion

Community recruitment

Our recruitment methods reached individuals in the community in need of support i.e. people with diagnostic depression, anxiety and impaired social function (Table 1), with chronic symptoms of >5 years, but with 50.7% not currently on prescribed medication and only 45.3% currently attending their GP (Table 1). This is in line with previous research that suggests that less than 50% of individuals with depression in communities seek help from their GP.[4]

Our recruitment approach did not exclude people with higher levels of depression – in line with our previous work.[16,35] This approach tends to differ from that taken in many NHS services such as IAPT which often exclude people from low intensity therapies. However, recent work by Farrand and Woodford[36], suggest that those with higher depression scores can benefit from using low intensity approaches.

When compared with a recently published trial of CBT delivered in a primary care setting, our recruitment methods reached a greater proportion of individuals who were unmarried (49.3% versus

19.0%[7]; 35% of Scottish adults are unmarried), had chronic symptoms of depression >2 years (80.9% versus 59.0%), and were of non-white ethnic origin (8.5% versus 2.0%; 3.3% of the Scottish population is non-White).[37] Although men were underrepresented in the study (29.7% were male compared to 48% in the population), the sample was representative of the Scottish population in relation to age. This is seen in the fact that the age range in the sample had a wide range of 20-80 years old. In addition, the mean age was 46.6 years while the most populated age category in Scottish adults is 45-59 years.[37] This fits with previous research on self-referral where community methods of recruitment engaged people who more accurately reflected the make-up of the community than those referred by GPs.[38] As people were recruited from the community, the findings of this research are widely applicable.

Findings in context

At the 6-month follow-up, statistically significant between-group differences were observed for all outcome measures demonstrating that the LLTTF intervention was effective in improving symptoms of depression, anxiety and social function (Table 3, Figure 2). A clinically important response in PHQ-9 has been described variously in previous studies as: (a) a reduction of 5 points or more; or (b) a post-treatment score of ≤9; or (c) a minimum of 50% improvement in PHQ-9 score.[24] The findings for each of these measures show high recovery rates. In those scoring 10 or more, the PHQ-9 reduced by 37.4% (-5.5 points) in IA group from baseline to 6-months (14.7 versus 9.2 points; Table 2). Clinically this indicates a reduction from moderately-severe to mild depression and suggests that the intervention was effective for participants with more severe depression.

Significant between-group differences were observed for social functioning, with the IA group improving their score for social function on the WSAS. An individual's ability to conduct normal social roles is an integral component of their quality of life.[39] Depression and anxiety have a negative effect on personal and professional relationships via loss of energy, reduced self-esteem and increased distress. Therefore the ability of the LLTTF classes to improve social functioning has the potential to impact on individuals' long-term quality of life.

Intervention Delivery

Participant satisfaction with LLTTF was high (mean CSQ-8 score of 24.3 (sd 5.1), in line with RCT's undertaken in both primary care (25.3 (sd 5.8)[40] and outpatient settings (24.4 (sd 3.5).[41] The charity delivering the classes is experienced in working with adults with depression and anxiety.

Working alongside *Action on Depression*, an established and well equipped voluntary organisation, was a strength of our intervention.[42]

Economic Analysis

The intervention was effective in improving symptoms of depression, anxiety and social function whilst being cost-neutral and available at an ICER below the NICE thresholds for funding. CBT delivered within specialist care can be resource intensive and waiting lists can be long. Therefore community-based group CBT interventions, such as the Living Life to the Full classes, can provide an alternative route of management, to larger groups of patients, at no additional cost to the health service.

Strengths and Limitations

This is the first RCT to explore the effectiveness and cost-effectiveness of guided self-help CBT classes for depression delivered in a community setting. The study design, class-based delivery, co-working with a charity, and the community recruitment approach show high ecological validity and has the potential to be readily transferred into practice. Our recruitment strategy ensured an adequate sample size of individuals with high baseline PHQ-9 scores to allow for analysis of intervention effects on increasing severity of symptoms. No participants were recruited from an NHS setting allowing us to demonstrate the effectiveness of reaching individuals in need of support in the community. However, this study has some limitations. As with many similar studies, an issue is the choice of control group. The role of a control group is to protect internal validity[43]. A delayed access control achieves this, and a review of community-based research[36] recommends a delayed access control design as a way of maximising recruitment and retention. An alternative would have been to have a two arm study comparing the classes with an alternative existing class-based intervention to match any socialisation aspect across the arms. However such a change would require far larger sample sizes, and significantly larger funding, Additionally and importantly, such an intervention is not routinely available in community settings, and does not reflect real-world experience. The current study design has the advantage of helping understand what happens to people in communities who are receiving treatment as usual. However the design could be improved by including a longer term follow-up (≥12-months) to examine whether the positive findings at 6-months were maintained long-term would be valuable. As a small academic trial, the resources available were insufficient to support separate staff for notifying participants of their allocation group, arranging treatment classes, supporting the delivery of classes, and collection of outcome

data. Outcome data were collected by self-completed questionnaires, so whether or not the researchers were aware of treatment groups should have had little or no impact. Finally, it is possible that the positive effect of LLTTF may have been due to session content, availability of group-based support or a combination. Further exploration of long-term maintenance and a better understanding of process issues are therefore required.

Conclusions

The LLTTF intervention demonstrated that low-intensity CBT classes delivered within a community setting are effective and cost-effective in the management of depression, anxiety and impaired social function, and can provide an alternative treatment option for use in primary care and community settings. Community-based recruitment can successfully reach individuals in need of support and may provide an alternative route of help for people not engaging with the health service, with only 45% of participants seeing their GP for support. Community-based interventions are a promising addition to mental health care provision and warrant further investigation.

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Conflict of interest

Professor Chris Williams is president of BABCP- the lead body for CBT in the UK, and a CBT researcher and trainer. He is also author of a range of CBT-based resources that address anxiety, depression and other disorders. These are available commercially as books, cCBT products, and classes. He is developer of the LLTTF classes evaluated in this study. He receives royalty, and is shareholder and director of a company that commercialises these resources. C-AM, LM, CH, AM and JM have no conflict of interests to declare.

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Tables and Figures

Figure 1. CONSORT diagram of participant flow through the intervention.

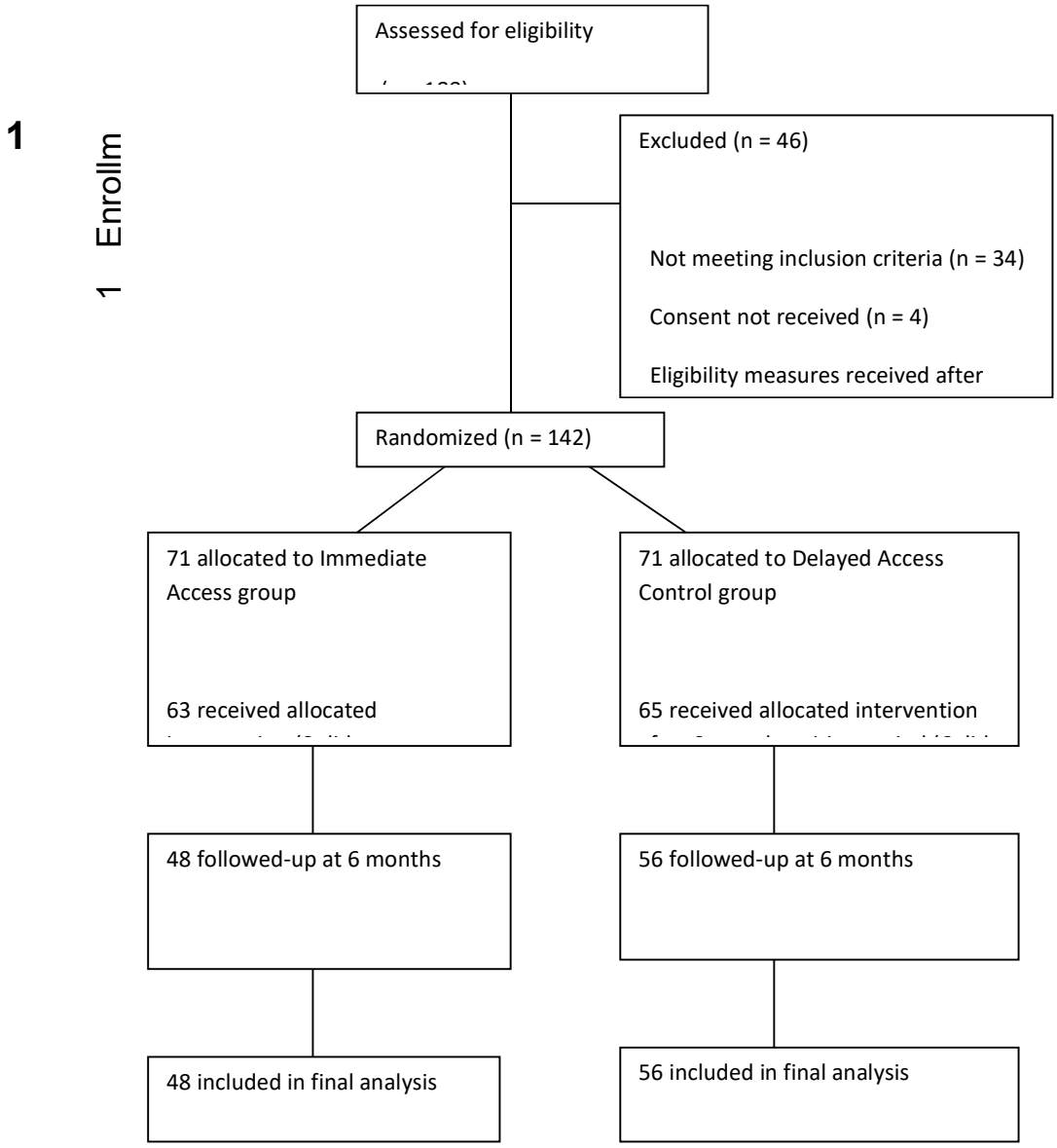

Table 1. Characteristics of participants at randomisation.

Characteristic	*Overall % (n=142)*	*IA (n=71)*	*DAC (n=71)*
Mean age in years (sd)	46.6 (13.5)	46.8 (14.0)	46.5 (13.2)
Gender: % male (n)	29.7 (38	42.3 (30)	22.5 (16)
Medication: % yes (n)	49.3 (70)	46.5 (33)	52.1 (37)
Current GP input: % yes (n)	46.5 (66)	49.3 (35)	43.7 (31)
MINI diagnostic interview	n=93	n=41	n=52
– Current	2 (2)	0 (0)	2 (4)
– Past	11 (12)	7 (17)	4 (8)
– Recurrent	52 (56)	21 (51)	31 (60)
– Current & Past	26 (28)	13 (32)	13 (25)
– None	2 (2)	0 (0)	2 (4)
Chronicity of symptoms: %(n)			
– < 5 years	31.9 (45)	31.0 (22)	32.9 (23)
– ≥ 5 years	68.1 (96)	69.0 (49)	67.1 (47)
Marital status: %(n)			
– Married	49.3 (70)	47.9 (34)	50.7 (36)
– Single	27.5 (39)	26.8 (19)	28.2 (20)
– Separated/Divorced	19. (27)	18.3 (13)	19.7 (14)
– Widowed	4.2 (6)	7.0 (5)	1.4 (1)
Ethnicity: % (n)			
– White	91.5 (130)	93.0 (66)	90.1 (64)
– Mixed	3.5 (5)	2.8 (2)	4.2 (3)
– Asian/Asian British	2.1 (3)	1.4 (1)	2.8 (2)
– Black/Black British	1.4 (2)	2.8 (2)	0.0 (0)
– Chinese			
– Other			

	0.7 (1) 0.7 (1)	0.0 (0) 0.0 (0)	1.4 (1) 1.4 (1)
Education – Post-graduate degree – Under-graduate degree – HNC, HND, SVQ or RSA – Higher grade or equiv – Standard grade or equic – No formal qualifications	15.6 (22) 24.8 (35) 22.0 (31) 12.1 (17) 16.3 (23) 9.2 (13)	12.9 (9) 27.1 (19) 22.9 (16) 14.3 (10) 12.9 (9) 10.0 (7)	18.3 (13) 22.5 (16) 21.1 (15) 9.9 (7) 19.7 (14) 8.5 (6)

Table 2. Main outcome measures for both groups at baseline and 6-month follow-up.

	Baseline *Mean (sd)*			*Follow-up at 6-months* *Mean (sd)*		
	All participants (n=128)	*IA (n=63)*	*DAC (n=65)*	*All participants (n=104)*	*IA (n=48)*	*DAC (n=56)*
PHQ-9	15.2 (5.4)[1]	14.7 (5.2)[1]	15.7 (5.6)[1]	11.5 (7.1)[3]	9.2 (6.2)[2]	13.6 (7.3)[3]
GAD-7	12.6 (4.9)[4]	11.8 (4.5)[4]	13.3 (5.1)[4]	9.4 (5.8)[4]	7.6 (5.7)[5]	10.9 (5.5)[4]
HADS Depression	10.9 (3.9)[7]	9.8 (3.8)[6]	11.9 (3.7)[7]	8.8 (4.9)[6]	7.0 (4.5)[8]	10.2 (4.8)[7]
HADS Anxiety	12.9 (4.2)[7]	12.2 (4.0)[7]	13.5 (4.4)[7]	11.1 (4.9)[7]	9.5 (5.2)[6]	12.5 (4.3)[7]
WASAS	26.2 (7.7)[9]	25.1 (7.9)[9]	27.1 (7.5)[9]	22.0 (11.0)[9]	18.7 (11.4)[10]	24.8 (9.9)[9]

[1]Moderately-severe depression; [2]Mild depression; [3]Moderate depression; [4]Moderate anxiety; [5]Mild anxiety; [6]Borderline depression/anxiety; [7]Depression/anxiety; [8] No depression/anxiety; [9]Moderately-severe psychopathology; [10]Moderate psychopathology

Table 3. Between-group differences from baseline to 6-month follow-up adjusted for baseline scores, age, sex, medication use and chronicity.

Outcome	*n*	*Coefficient*	*95% CI*	*P-value*
PHQ-9 score	103	-3.64	(-6.06, -1.23)	0.004
GAD-7 score	99	-2.83	(-5.03, -0.64)	0.012
HADS depression score	97	-2.83	(-4.67, -0.99)	0.003
HADS anxiety score	97	-2.39	(-4.33, -0.45)	0.017
WSAS score	96	-5.31	(-9.35, -1.27)	0.011

Figure 2. Means and 95% confidence intervals of PHQ-9, GAD-7, HADS depression, HADS anxiety and WASAS scores for both groups at baseline and 6-month follow-up.

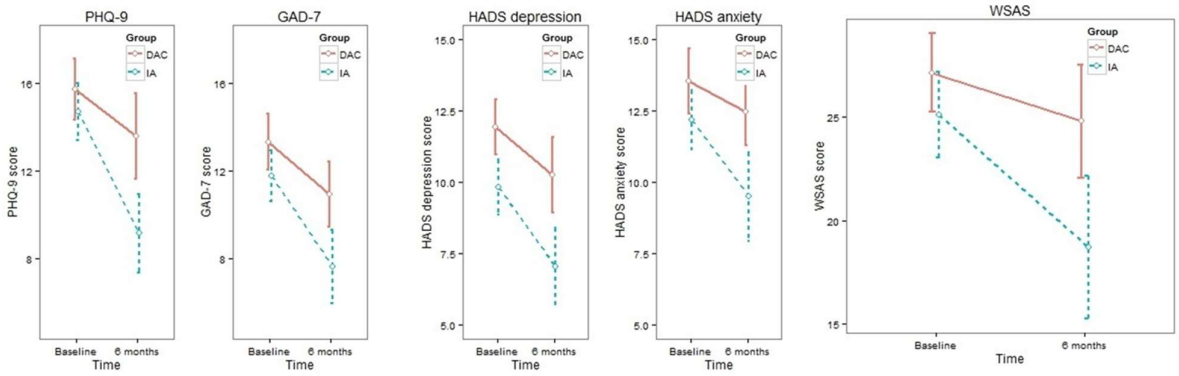

Figure 3. Cost-effective ratio (difference in cost / difference in QALY) and willingness to pay (£)

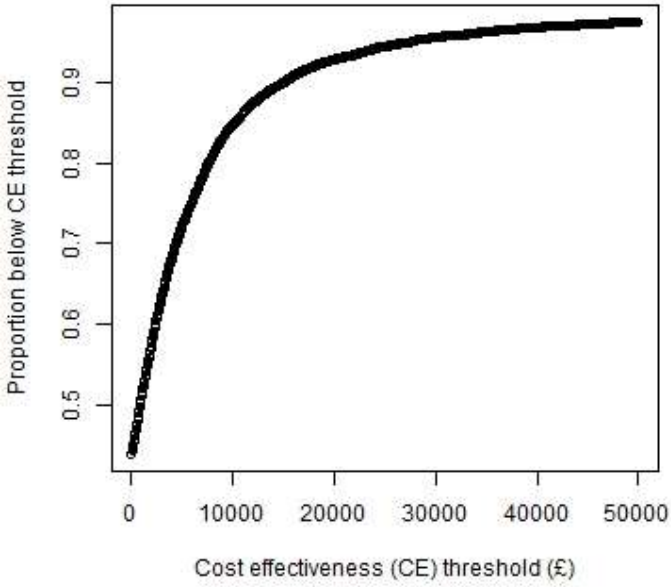

Figure 4: Cost and QALY - bootstrapped using stratified sampling and recycled predictions

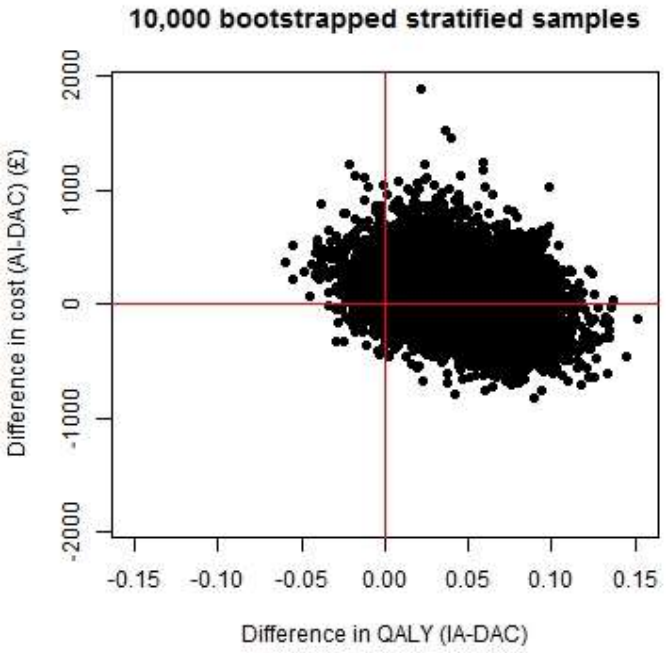
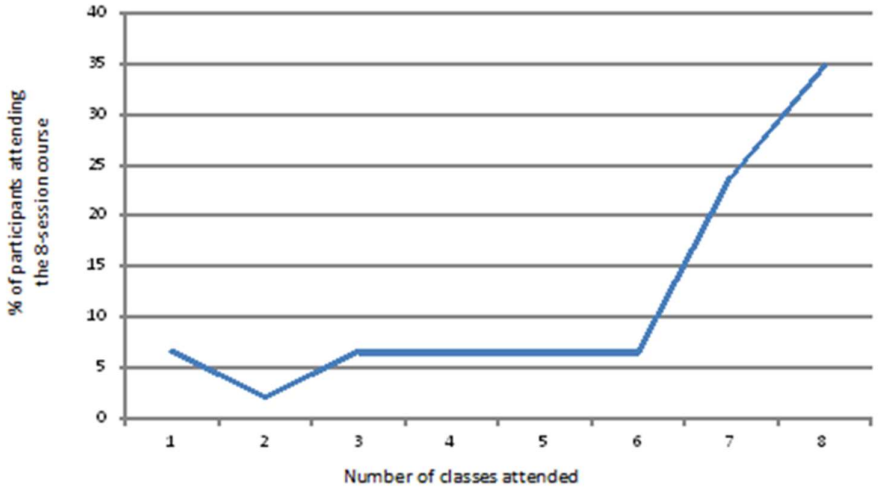
Figure 5. Attendance survival curve.