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Final report form	**CSO reference number:** CZH/4/738

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Project title: A randomised controlled trial of a community based group guided self-help intervention for low mood and stress.	
Start date: 9th July 2012	**Finish date:** 8th January 2014

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Final word count: 3549

Final report:

1. Summary

The National Institute for Health and Clinical Excellence (NICE) recommends cognitive behavioural therapy (CBT) for mild to moderate depression [1]. Traditional CBT consists of 12-20 one hour sessions with a CBT expert and can be delivered in community settings [2]. However, it remains difficult to provide *high intensity* specialist CBT (HI) and waiting lists are long. An alternative is to supplement HI delivery with *low intensity* CBT (LI) [3]. This includes the delivery of written CBT resources (bibliotherapy) with practitioner support, usually offered one-to-one. Support can also be provided in classes, but currently there are few face-to-face LI classes available and none have been adequately tested in an RCT setting. This study is the first to evaluate CBT self-help resources delivered with LI support/guidance via short, weekly, face to face, small group classes delivered through the voluntary sector. It demonstrated that the Living Life to the Full (LLTTF) classes delivered within a community setting were effective, cost effective and acceptable in the management of depression, anxiety and impaired social function. Community-based recruitment can successfully reach individuals in need of support including those not currently receiving GP support for low mood. The LLTTF classes provide an alternative treatment option for use in primary care and community settings.

2. Original aims

Primary question:
Do the LLTTF classes result in an improvement in symptoms of depression and anxiety at 6 months compared to a delayed access control group, as measured by the Patient Health Questionnaire (PHQ-9) [4] and Generalised Anxiety Disorder assessment (GAD-7) [5]?

Secondary questions:
a) Do the LLTTF classes result in an improvement in symptoms of depression and anxiety at 6 months for those with a baseline PHQ-9 score ≥10 and those with a score of 5-9, compared to a delayed access control group, as measured by the PHQ-9 and GAD-7?
b) Do the LLTTF classes result in an improvement in social function at 6 months compared to the control group as measured by the Work and Social Adjustment Scale (WSAS) [6]?
c) Are the LLTTF classes more cost effective than the delayed access control?
d) Are the LLTTF classes more satisfactory to participants than delayed access control?

3. Methodology

A pre-post design RCT with delayed access control at 6 months follow-up.

Participants: Individuals with depressive symptoms were recruited via multiple community-based methods (websites, phone support line, newsletters and local groups), supplemented by advertisements in the Metro free newspaper. Recruitment included participants who were, and were not, actively seeking treatment via the NHS. No participants were recruited via the NHS. Ethics approval included, but did not use, posters and Google adverts.

Inclusion criteria: Individuals aged≥16yrs with at least mild depressive symptoms defined as a PHQ-9 score of 5 or more.

Exclusion criteria: Age <16yrs. Participants were excluded if they could not read, speak and understand English, travel to the classes, did not consent to abide by normal social etiquette within the classes or had a PHQ-9 score <5.

Setting & Procedure: Promotion material directed those individuals interested in participating to contact the Research assistant (RA) by phone or email for further details.

Potential participants were sent copies of the Participant Information Sheet, Eligibility Questionnaire, PHQ-9, GAD-7, Hospital Anxiety and Depression Scale (HADS) [7] and Consent Form. The eligibility questionnaire collected basic demographic information in addition to information regarding previous or ongoing mental health treatment, ability to travel and attend classes and chronicity of their low mood. Returned questionnaires were assessed for eligibility. Eligible participants were invited to participate in a MINI diagnostic interview [8] to describe the sample population (not as an outcome measure). Participants had the option of declining the MINI interview whilst still participating in the study. Baseline measures were collected once a sufficient numbers of eligible participants were recruited to fill two group classes. Participants were then randomised to either an Immediate Access (IA) or Delayed Access Control (DAC) group. Randomisation took into account timing and location of classes, and severity of depression as measured by the PHQ-9.

Intervention: Living Life to the Full classes (LLTTF): LLTTF class sessions lasted 1.5 hours and covered a variety of guided self-help topics teaching life-skills for depression and anxiety. Sessions were presented in library rooms using a standard presentation set and support scripts. Each session was accompanied by booklets and worksheets. Adherence to the intervention method was assessed by a RA sitting in on a random selection of classes and rating the delivery of key points.

Follow-up: (see Table 1) The primary outcome of change in symptoms was measured at 6 months by the PHQ-9 (depression) and GAD7 (anxiety) using an intention to treat (ITT) analysis. We also used HADS as a secondary check of depression and anxiety as it is widely used in similar research papers. The WSAS was used to assess levels of social functioning and the Client Satisfaction Questionnaire (CSQ-8) [9] was administered post intervention as a measure of satisfaction with the intervention. The Client Service Receipt Inventory (CSRI) [10] and EQ5D [11] were used to measure use of services and current state of health, and were used for economic analysis.

Statistical power and sample Size: The primary analysis compared changes in PHQ-9 and GAD-7 scores at 6 months between intervention groups in all participants using an intention to treat analysis. Blinded data from our previous pilot study showed that for those with a PHQ-9 ≥10 at baseline, mean PHQ-9 scores reduced from 17.7 to 10.8 points post-intervention. Based on a two-sample t-test, a sample size of 27 participants per arm is required to have 90% power to detect a between group difference in changes over baseline of 5.5 points. In the pilot, follow-up data at the primary end point were available for 65% of those randomised and one third of participants had PHQ-9 scores less than 10 points at baseline. We therefore required to randomise 126 participants in total (two groups of 63).

Statistical analyses: The primary analysis used analysis of covariance (ANCOVA), testing the difference between groups in PHQ-9 and GAD-7 scores in all participants at 6 months with adjustment for baseline values, stratification variables and other adjustment variables. This is more efficient than a two-sample t-test, increasing the power of the study. An intention to treat approach was used. Secondary analyses were carried out for those with PHQ-9 scores ≥10, and for those with scores less than 10, at baseline. The model for all participants was extended to assess the impact of baseline participant characteristics including age, gender, antidepressant use and measures of compliance with the intervention. Similarly, regression methods were used for other outcomes. Simple and multiple imputation methods were explored as a secondary analysis for the primary outcome to assess the sensitivity of the main study findings to alternative assumptions regarding missing data.

Economic analysis: The CSRI and EQ5D were used to measure use of services and current state of health. Economic analysis was performed from a health service perspective as recommended by NICE [12]. 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 so as to include the threshold used by NICE.

The study obtained ethical approval from the University of Glasgow Ethics Committee and is a registered trial (Current Controlled Trials - ISRCTN86292664).

Table 1: Measures taken during the study.

Screening	**Baseline**	**6 months (IA)**	**6 months (DAC)**
PHQ-9 GAD-7 HADS Demographics MINI diagnostic interview	PHQ-9 GAD-7 HADS WSAS CSRI (6 months retrospective) EQ5D	PHQ-9 GAD-7 HADS WSAS CSRI EQ5D CSQ-8 "Your experience of attending the 'Living Life to the Full' class" Questionnaire	PHQ-9 GAD-7 HADS WSAS CSRI EQ5D

Changes to the methodology or delivery of the project

Several minor adaptations were made to the intervention protocol.

1. We stated in our original protocol that we would invite those who completed baseline measures but failed to attend the classes or return for follow-up measures, to take part in a qualitative interview with the researcher. Failure to take up the intervention in cohort 1 was limited (n =10) and therefore it was not considered productive to pursue this aspect of the study as we would achieve a very small sample. This amendment was approved by Diane Brockie on 13/03/13.

2. As mentioned in our 6-month progress report, in order to thank participants for their time in returning questionnaires we provided a low cost Amazon/Tesco voucher in return for completed follow-up questionnaires. This was expected to improve follow-up rates and help us achieve the target of >70% response rate. Ethical approval was granted for this and vouchers were purchased from the travel budget which was significantly under spent. This amendment was approved by CSO.

3. Our research assistant, Carrie-Anne McClay, went on maternity leave in July 2013. The vacancy was advertised and Dr Lynsay Matthews was employed to continue with the research assistant duties. The new research assistant was added to the ethics application and details were sent to CSO.

4. It was recognised that the DAC group received their class intervention *following* collection of the 6-month follow-up measures. We therefore omitted the CSQ-8 outcome measure for the DAC follow-up as they had not yet participated in any classes. Based on feedback during the writing of the protocol paper it was suggested the final two aims be clarified to c) Are the LLTTF classes cost effective?, and d) Are the LLTTF classes satisfactory to participants? This was discussed with CSO and felt appropriate.

4. Results

Participant characteristics

Figure 1 presents a CONSORT diagram of participant flow through the intervention. One hundred and forty two participants were randomised to the IA and DAC group (n=71 per group). We ensured that the required number of participants scoring 10+ on the PHQ-9 had entered the study before ending recruitment. At 6-month follow-up a response rate of 71.8% (n=102 of 142) was obtained. Demographic data at randomisation are presented in Table 2. Baseline measures are presented in Table 3. No significant differences were found between groups or in those participants who dropped-out prior to follow-up.

At baseline 93.0% (n=132 of 142) of participants reported a PHQ-9 score ≥10; 68.1% (n=96 of 142) had chronic symptoms of depression and/or anxiety for ≥ 5 years; and 49.3% (n=70 of 142) were using prescribed anti-depressant medication. No difference was observed in the proportion of antidepressant medication use at baseline between the IA and DAC group (46.5% versus 52.1% respectively, p=0.615). Participants using medication scored higher at baseline on PHQ-9 (16.5 versus 14.0), GAD-7 (11.0 versus 10.3) and WSAS (28.4 versus 24.0) than participants not using medication. The MINI diagnostic interview was completed by 65.5% (n=93 of 142) of participants, of which 97.8% (n=91 of 93) were rated as having a past, current or recurring major depressive episode (Table 2).

Class Delivery

A total of 17 LLTTF classes were monitored by the RA for consistency and fidelity to the class protocol. 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.

Main Outcomes

Table 3 and Figure 2 present outcome measures for PHQ-9, GAD-7, HADS depression, HADS anxiety and WSAS at baseline and 6-month follow-up for both IA and DAC groups. No effects were found for two-way interactions of treatment group with gender, age, chronicity of symptoms, medication use or PHQ-9 score at baseline. Sensitivity analysis, as a secondary analysis, did not affect the results. Results were not sensitive to choice of adjustment variables or imputation model.

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

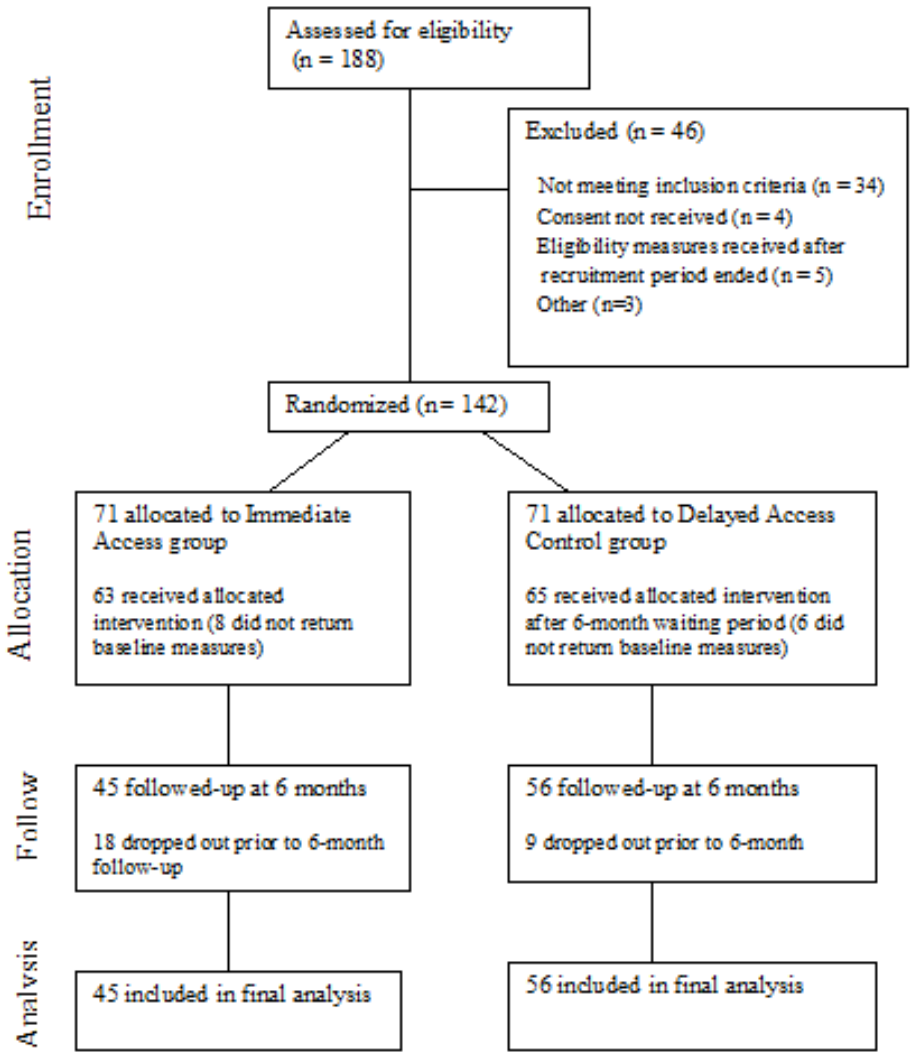


Table 2. Characteristics of participants at randomisation.

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 major depressive episode	2 (2)	0 (0)	2 (4)
– Past episode	11 (12)	7 (17)	4 (8)
– Recurrent episode	52 (56)	21 (51)	31 (60)
– Current & past episode	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	0.7 (1)	0.0 (0)	1.4 (1)
– Other	0.7 (1)	0.0 (0)	1.4 (1)
Education			
– Post-graduate degree	15.6 (22)	12.9 (9)	18.3 (13)
– Under-graduate degree	24.8 (35)	27.1 (19)	22.5 (16)
– HNC, HND, SVQ or RSA	22.0 (31)	22.9 (16)	21.1 (15)
– Higher grade or equiv	12.1 (17)	14.3 (10)	9.9 (7)
– Standard grade or equiv	16.3 (23)	12.9 (9)	19.7 (14)
– No formal qualifications	9.2 (13)	10.0 (7)	8.5 (6)

Table 3. Main outcome measures for both groups at baseline and 6-month follow-up (ITT).

	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]
WSAS	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

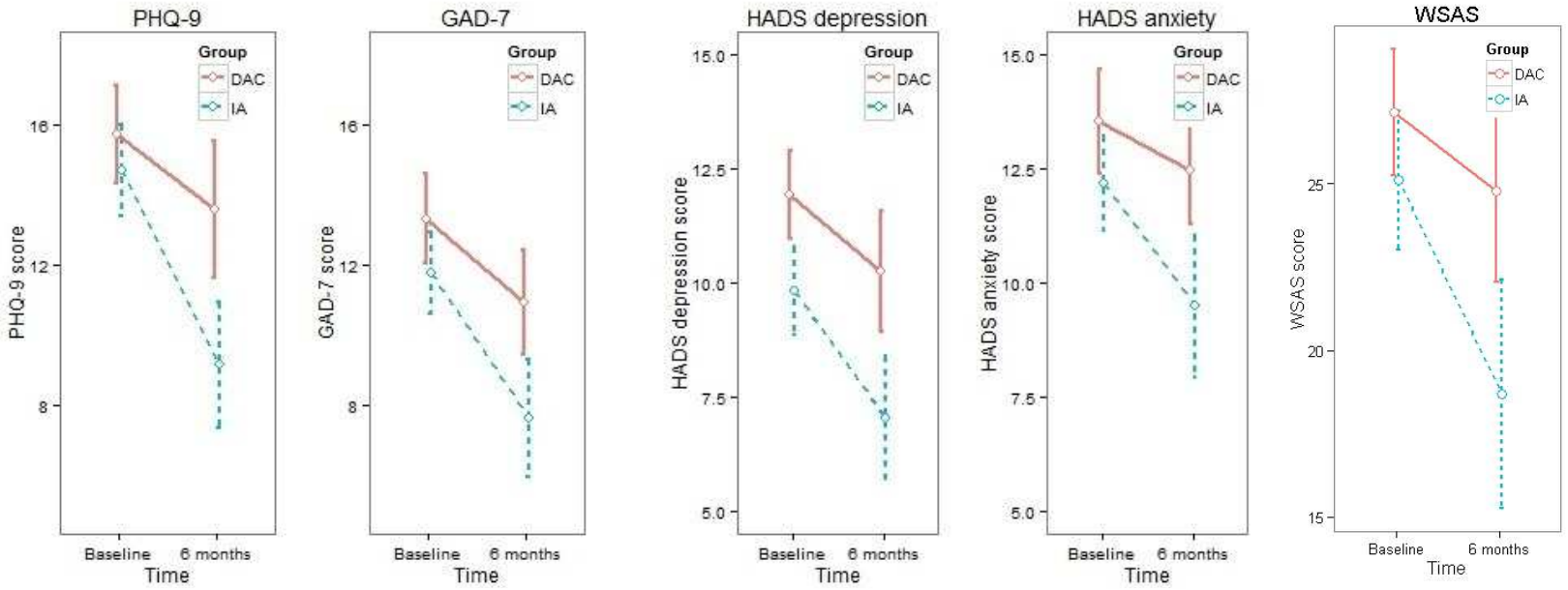
- ***Primary Outcomes***

Change in measures of depression and anxiety: A significant between-group difference was observed in both primary outcomes of mean change in PHQ-9 score (-3.64; 95%CI -6.06, -1.23; p=0.004) and mean change in GAD-7 score (-2.83; 95%CI -5.03, -0.64, p=0.012) (Table 4). Additional measures of depression and anxiety (HADS) also significantly improved at 6-months from baseline (Table 4, Figure 2).

Table 4. 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 WSAS scores for both groups at baseline and 6-month follow-up (ITT*).

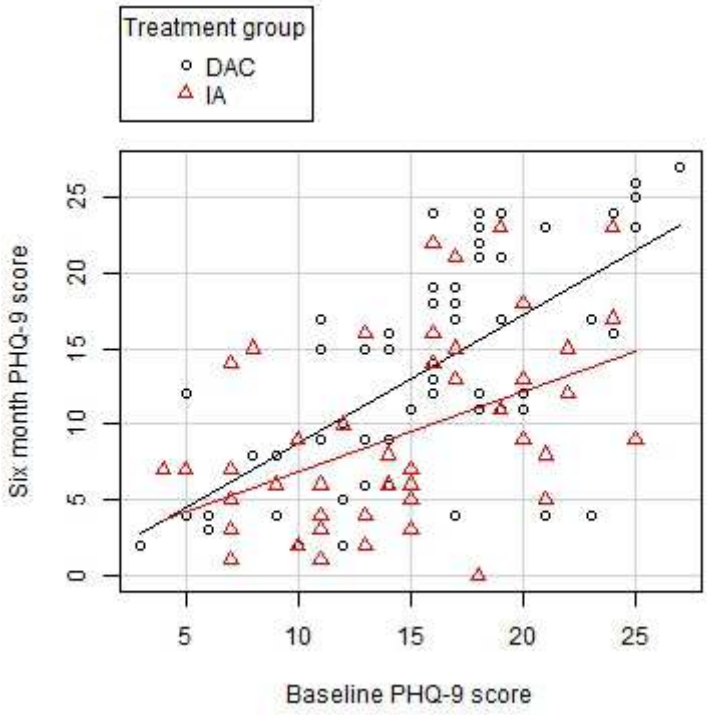


* Intention to treat analysis

- ***Secondary Outcomes (Aims a-d)***

a) Change associated with PHQ-9 ≥10 at baseline: Secondary analysis of PHQ-9 scores ≥10 demonstrated a significant treatment effect with increasing baseline PHQ-9 score (Figure 3; interaction p=0.045). Participants with a baseline PHQ-9 score ≥10 (n=86) significantly improved their PHQ-9 at 6-month follow-up (-5.37; 95%CI -8.33, -2.42, p<0.001) compared with those with baseline PHQ-9 scores <10 (n=18), who showed no change at follow-up (1.15; 95%CI -3.33, 5.62, p=0.591). A three-fold increase was observed in the number of IA participants with PHQ scores ≤9 (clinical cut-off for depression) at 6-month follow-up compared to baseline (59.6% versus 17.4%).

Figure 3. Interaction effect of baseline PHQ-9 scores and treatment group on 6-month PHQ-9 scores.



b) Change in social function: A significant between-group difference was observed for social function as measured by WSAS at 6-months from baseline (-5.31; 95%CI -9.35, -1.27, p=0.011) (Table 4, Figure 2).

c) Cost-effectiveness: Total NHS treatment costs (including medication and inpatient, outpatient, NHS24 and A&E appointments) in the 6-months *prior* to the LLTTF intervention were £907 and £802 for the IA and DAC group, respectively, and reduced during the 6-month intervention to £780 (£-127) and £740 (£-62), respectively. Cost-per-quality adjusted life year (QALY-CPQ) was analysed using stratified bootstrapping and recycled predictions. The probability of CPQ being below a willingness to pay threshold of £20,000, £25,000 or £30,000 was 0.916, 0.940 and 0.952 respectively (Figure 4). Figure 5 demonstrates that in spite of the additional costs of delivering the classes, the net result showed improved outcomes and high satisfaction at the same cost as not delivering the classes.

Figure 4: Cost-effective ratio (difference in cost / difference in QALY) and willingness to pay (£)

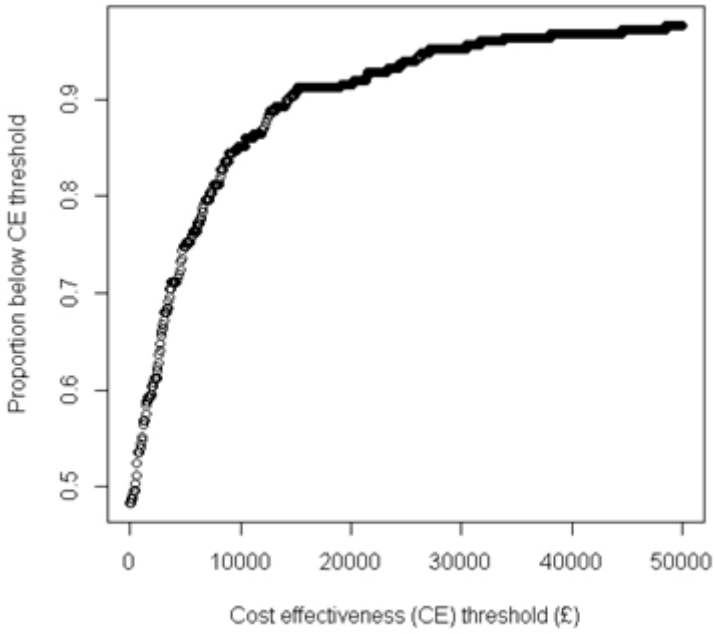
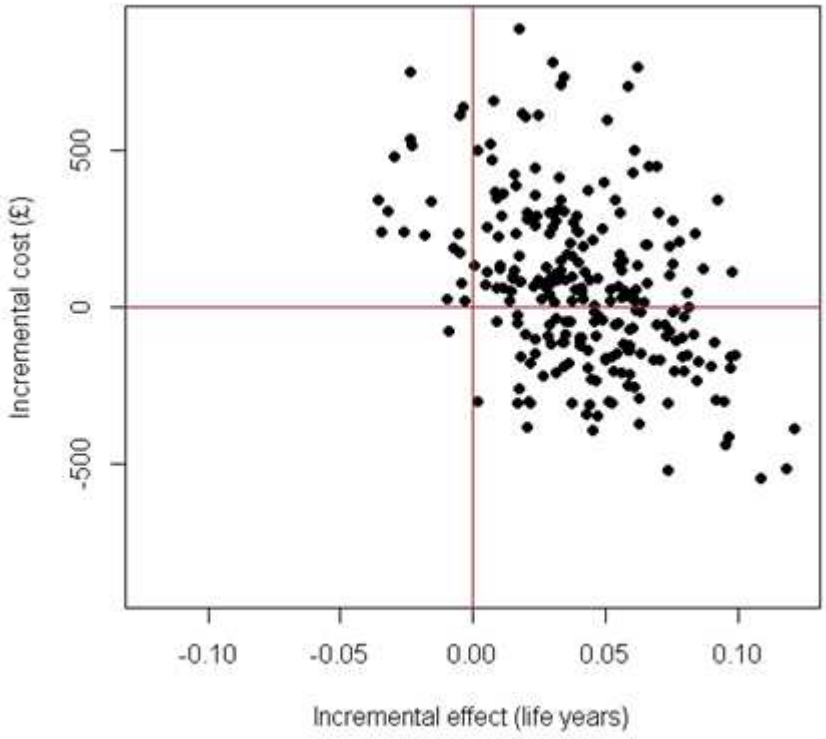


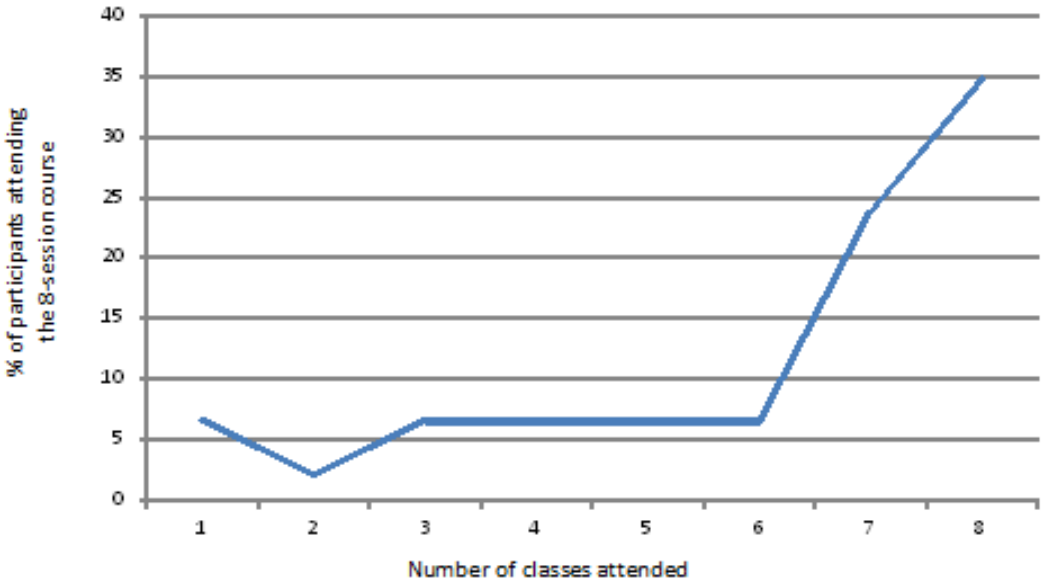
Figure 5: Incremental cost effectiveness scatterplot of LLTTF intervention



d) Attendance and Participant Satisfaction: In the IA group 35.2% (n=25 of 71) allocated to the IA group declined to attend classes and dropped-out of the research study. Reasons for drop-out included: no baseline measures (n=8); alternative treatment (n=5); lack of time (n=4); deteriorating mood (n=3); moved house (n=1); and no reason given (n=4). Of the participants who continued to participate, 93.5% (n=43) attended at least one of the LLTTF classes. On average, 78.3% (n=36) attended ≥4 sessions, with

34.8% (n=16) attending all 8 sessions (Figure 6). Mean participant satisfaction with the LLTTF classes (IA group) was 24.3±5.1 (n=47) as measured by the CSQ-8. 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% (n=36 of 44) of IA participants who returned class feedback forms.

Figure 6. Attendance at LLTTF classes (IA group).



Discussion

Participant characteristics: Key points

Community recruitment effectively reached individuals in need of support i.e. people with diagnostic depression, anxiety and impaired social function (Table 3), with chronic symptoms of >5 years, but with 50.7% not currently on antidepressant medication and only 45.3% currently attending their GP (Table 2). The use of antidepressants supports previous research suggesting <50% of individuals with depression seek help from their GP [13]. When compared with HI-CBT delivered in a primary care setting [2] our recruitment methods reached a greater proportion of individuals who were unmarried (49.3% versus 19.0%), had chronic symptoms >2yrs (80.9% versus 59.0%), and were of non-white ethnic origin (8.5% versus 2.0%) [2]. This fits with previous research on self-referral to services where self-referral engaged people who more accurately reflected the make-up of the community than those referred by GPs [14].

Main Outcomes: Key points

At 6-month follow-up, statistical and clinically 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 4, Figure 2). In particular, the PHQ-9 reduced by 37.4% (-5.5 points) in the IA group from baseline to 6-months (14.7 versus 9.2 points; Table 3). Clinically this is indicative of a reduction from moderately-severe to a mild depression category. Several levels have been suggested as a clinically important response in PHQ-9, including: (a) a reduction of 5 points or more; (b) a post-treatment score of ≤9; and (c) a minimum of 50% improvement in PHQ-9 score [15]. The findings are therefore clinically relevant in relation to criterion-(a) *and* criterion-(b), in which we observed a three-fold increase in the number of IA participants with PHQ scores ≤9 at 6-month follow-up compared to baseline

(59.6% versus 17.4%). The results were also approaching clinical significance in relation to criterion-(c) with an overall 37.4% reduction in PHQ-9 scores for IA participants.

Other Outcomes: Key points

Participants with increasing baseline PHQ-9 scores ≥10 significantly improved at 6-month follow-up cf. those with baseline PHQ-9 scores <10, demonstrating that LLTTF classes were effective for participants with greater symptoms of depression. At 6-month follow-up, significant between-group differences were observed for all other outcome measures and the LLTTF intervention was effective in improving symptoms of anxiety and social function (Table 4, Figure 2).

No differences were found in the treatment effect between genders suggesting that the LLTTF intervention was equally effective for males and females. Previous research has shown that males are a hard-to-reach group for depression management, and these findings show that community based approaches have potential to engage and treat this group [16]. No association was found with medication use at baseline. Our population is largely a chronic group, many of whom have not responded to medication. In our study, the majority of participants had symptoms for greater than 6-months (91.5%, n=130 of 142), of which 50.8% (n=66) were using prescribed medication. The positive findings of our study demonstrate that community based interventions can be effective in managing depression in participants who have not responded to pharmacological treatment alone.

Attendance and Participant Satisfaction: Key points

Participant satisfaction was high (mean CSQ-8 score of 24.3±5.1), supported by a high attendance rate during the 8-week course (Figure 4). Satisfaction with our community-delivered intervention is in line with RCT's undertaken in both primary care (25.3±5.8) [17] and outpatient settings (24.4±3.5) [18].

Economic Cost: Key points

The probability of the CPQ being below the cost-effectiveness threshold recommended by NICE (£20,000-£30,000) was high [12] (Figure 5). The intervention was effective in improving symptoms of depression, anxiety and social function whilst demonstrating a cost-neutral input by the health service (Figure 6).

5. Conclusions

The study demonstrated that LI, bibliotherapy-based CBT classes delivered within a community setting are effective in the management of depression, anxiety and impaired social function. Community-based recruitment can successfully reach individuals in need of support and may provide an alternative route of help for people who may not engage with the health service. The LLTTF intervention demonstrated cost-effectiveness and therefore provides an alternative treatment option for use in primary care and community settings. Community-based interventions are a promising addition to mental health care provision and warrant further investigation.

References cited in final report

1. National Institute for Clinical Excellent (NICE). Depression: Management of depression in primary and secondary care. CG90. London: National Institute for Clinical Excellence, 2009

2. Wiles, NJ, Thomas L, Abel A, Ridgway N, Turner NL, Campbell J. et al. Cognitive behavioural therapy as an adjunct to pharmacotherapy for primary care based patients with treatment resistant depression: results of the CoBalT randomised controlled trial. Lancet, 2013; 381(9864): 375-84.

3. Ridgway N & Williams C. Cognitive behavioural therapy for depression: An overview. Journal of Mental Health, 2011; 20: 593-603

4. Spitzer RL, Kroenke K, Williams JB. Validation and utility of a self-report version of the prime-MD: the PHQ primary care study. JAMA. 1999; 282:1737-1744.

5. Spitzer RL, Kroenke K, Williams JB, Lowe B. A Brief Measure for Assessing Generalized Anxiety Disorder: The GAD-7. Arch Intern Med. 2006;166:1092-7

6. Mundt JC, Marks IM, Shear KM & Greist JM. The Work and Social Adjustment Scale: a simple measure of impairment in functioning. The British Journal of Psychiatry, 2002; 180: 461-464

7. Zigmond AS, Snaith RP. The hospital anxiety and depression scale. Acta Psychiatr Scand, 1983; 67:361-70

8. Sheehan DV, Lecrubier Y, Sheehan KH, Amorim P, Janavs J, Weiller E, Hergueta T, Baker R, Dunbar GC. The Mini International Neuropsychiatric Interview (M.I.N.I.): the development & validation of a structured diagnostic psychiatric interview. Journal of Clinical Psychiatry,1998; 59: 22-33

9. Nguyen TD, Attkisson CC, Stegner BL. Assessment of patient satisfaction: Evaluation and Program Planning, 1983 ; 6: 299–314

10. Glick HA, Doshi JA, Sonnad SS, Polsky D. Economic Evaluation in Clinical Trials. Oxford University Press; 2007

11. The EuroQol Group. EuroQol-a new facility for the measurement of health-related quality of life. Health Policy,1990; 16:199-208.

12. National Institute for Clinical Excellence (NICE). NICE guide to the methods of health technology appraisal. London: NICE; 2004

13. Kohn R, Saxena S, Levav I, Saraceno B. The Treatment Gap in Mental Health Care. Bull of WHO 2004, 82: 811-890

14. Brown JSL, Boardman J, Whittinger N, Ashworth M. Can a self-referral system help improve access to psychological treatments? British Journal of General Practice, 2010; 60(547): 365-71.

15. McMillan D, Gilbody S, Richards D. Defining successful treatment outcome in depression using the PHQ-9: A comparison of methods. Journal of Affective Disorders, 2010; 127(1-3): 122-129

16. Emslie C, Ridge D, Ziebland S, Hunt K. Exploring men's and women's experiences of depression and engagement with health professionals: more similarities than differences? A qualitative interview study. *BMC Fam Pract,* 2007; 8: 43.

17. Richards DA, Hill JJ, Gask L, Lovell K, Chew-Graham C, Bower P, et al. Clinical effectiveness of collaborative care for depression in UK primary care (CADET): cluster randomised controlled trial. BMJ, 2013; 347: f4913.

18. Houghton S, Saxon D. An evaluation of large group CBT psycho-education for anxiety disorders delivered in routine practice. Patient Educ Counsel, 2007; 68: 107-110.

19. McClay C-A, Morrison J, McConnachie A, Williams C. A community-based group-guided self-help intervention for low mood and stress: study protocol for a randomized controlled trial. *Trials,* 2013; 14: 392.

6. Importance to NHS and possible implementation

Our community-based RCT demonstrated that guided self-help CBT classes are an effective method of managing individuals with depression and anxiety. Current options for NHS-based treatment of depression and anxiety include traditional HI-CBT which is associated with long waiting lists. This study shows that alternative LI methods of CBT delivery are an option, with the potential of increasing both throughput and reach in the NHS. Findings provide insight into how similar interventions can be implemented within the community. Delivery via the voluntary sector was feasible and acceptable. *Action on Depression* were experienced in working with low mood and had staff and volunteers who competently delivered the intervention. This approach can be utilised as a wider resource open to both NHS referral and self-referral.

7. Future research

Several avenues of further research are identified. Firstly, it is important to explore long-term effectiveness of the classes beyond 6 months. Secondly, older adult and young people versions of the classes exist, and it is important to test whether they are also effective with these different age groups. Finally, the same content is available for free online at www.llttf.com and the impact of this site needs to be formally evaluated.

8. Dissemination

Dissemination of key findings will include an executive summary, open access journal publications and conference presentations. To date we have published the trial protocol in an open-access journal [19]. The aim of this paper was to provide fellow researchers and health professionals with the necessary detail to undertake similar interventions within a community setting. Secondly, our main outcome paper is under preparation and will be submitted to a high impact journal in addition to GP and psychiatry conferences. On publication a copy will be sent to NICE and SIGN and we will liaise with the University Press Office and CSO to see if the publication warrants a Press release. Additional routes of dissemination are planned. Study outcomes will be presented to participants via newsletters and the AOD website. We will disseminate findings on the www.llttf.com website which has around 20,000 signed up members including about 6000 practitioners. Therefore, both the professional community and individuals with depression will be made aware of the study and its findings.

9. Research workers

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Professor Jill Morrison, Professor of General Practice, General Practice and Primary Care, University of Glasgow

Dr Alex McConnachie, Assistant Director of Biostatistics, Robertson Centre for Biostatistics, University of Glasgow

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Dr Lynsay Matthews, Research Assistant, Mental Health and Wellbeing, University of Glasgow

Mr Stuart Rae, Research Volunteer, Mental Health and Wellbeing, University of Glasgow

10. Financial statement

We can confirm that the study was completed within the time and budget approved by CSO. Our final financial statement is under preparation by Mr David Young of the 'Finance, Research and Other Services' department of the University of Glasgow. Mr Young will finalise the Statement of Expenditure on 6/1/13, following which our financial statement will be promptly submitted to CSO.

11. Executive summary (Focus on Research) attached as requested by CSO guidelines.