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Feasibility study of a new behavioural activation programme for young people with depressed mood.

Abstract

Background: Behavioural activation (BA) is effective in adults with depression but the evidence for young people (YP) is less clear. We aimed to develop and test a new co-produced BA programme.

Method: In *phase one (2014 to 2015 inclusive)*, we co-developed with young people attending specialist child and adolescent mental health service (CAMHS) an 8-session BA workbook. We then tested this with 15 YP with depression and other co-morbidities. Satisfaction was good from both YP and staff, and 9 YP reported improvement in mood.

In Phase two (2019 to 2020 inclusive) we did a mixed method study in two specialist CAMHS, with BA being offered to YP by less experienced staff. During covid-19 we developed our website for blended BA therapy.

Results phase two: 51 YP were offered BA; 15 declined to take part. 36 consented with 3 dropping out after consent. 33 YP (mean age 14.6, 12 males, 24 females) continued treatment with BA attending a mean of 6.6 sessions. Youth-rated Mood and Feeling Questionnaire (MFQ) mean score decreased from 43.2 to 27.6, and Clinician Global Assessment Score (CGAS) mean score increased from 52.3 to 69.8. 16 young people were discharged from the service. Risk reduced in 9 of 12 YP with high risk initially.

Conclusions: Our co-developed BA programme appears useful and effective in this open study. Less experienced staff were able to use BA and this may reduce secondary waits for more specialist therapy. More research is needed about BA and it's place in specialist CAMHS.

Key points:

- There is limited research about BA as a discrete therapy for young people with depression. In contrast, BA for adults has an established evidence base.
- This co-developed BA programme designed for use in specialist CAMHS and for young people with moderate and severe depression, shows some initial promise (effectiveness and utility). The open design limits findings and further research is needed, such as mixed method randomised controlled trials with economic analysis.
- This BA programme provides eight workbooks, training, a fidelity measure, and digital materials for future clinical and research use. Less experienced clinicians can be trained in BA using these materials.

Key words: adolescence, depression, behaviour therapy, implementation, qualitative methods, service development

Introduction

Adolescent depression is common (Sadler et al., 2018), and cost-effective first-line psychological treatments are needed to meet the demand for services in the UK (Children's Commissioner, 2020). There is an urgent need to train less specialist practitioners to deliver interventions to increase access to therapy and reduce waiting times for more specialist care (Health Education England, 2017). BA may be an intervention that could provide both an effective intervention and be delivered by less experienced clinicians.

Behavioural activation (BA) is an intervention with a theoretical framework that proposes that increasing engagement in meaningful activity results in improved mood. Key parts of BA include: socialisation to the model to understand the "depression trap" and how activities, aligned to values, can help recovery; values and goal clarification; planned stepwise activity scheduling that are supported by key family, peer and professionals (e.g. staff in school); and dealing with avoidance (barriers) to activity scheduling. BA shows promise for young people with depression but has not yet been tested in large randomised controlled trials (RCTs). In contrast, a large RCT with adults, showed that BA (delivered by less experienced clinicians) was as effective in improving outcomes, and more cost-effective, than cognitive behavioural therapy (CBT) with a follow-up period of 18 months (Richards et al., 2017). A recent meta-analysis detailed that BA for adults is likely to be as effective as CBT (Stein et al., 2020).

The BA evidence base for young people is summarised in two systematic reviews (Tindall et al., 2017; Martin & Oliver., 2018). The reviews included case and feasibility

studies and a few small RCTs. The combined effect size for the four RCTs was 0.7, suggesting good efficacy of BA. However, this was derived from a small sample (n=160 for four collated RCTs), with considerable variation of focus (group versus individual), site (schools versus clinics), and young people's clinical characteristics between these studies. A variety of published and unpublished researcher developed BA manuals and programmes were detailed in the systematic reviews. Research is thus needed to address the poor evidence base, and to develop BA programmes designed for use in specific clinical settings. The adult literature has followed this process, as shown in the trials summarised in the review by Stein et al, (2020).

Methods

Our research started before the young peoples' systematic reviews were published, and before the two manuals ((McCauley et al, 2016; Reynolds et al, 2020) were published. We particularly wanted to focus on young people with moderate to severe depression attending specialist CAMHS and co-develop a programme with them that would be acceptable and to the staff delivering BA. On examining the other available BA programmes in 2019, we found substantial differences in delivery from our package; language use and style is different, particularly from the American programme. Our programme is shorter in length and focused on the use of the co-developed workbooks which incorporate an integral risk assessment and review process with embedded session feedback and goal-based outcomes. The other BA programmes use handouts for young people whereas we chose to develop workbooks. Our training guide is comprehensive and illustrated with vignettes of young people

with complex problems, and we have a fidelity rating scale designed specifically for the eight workbooks.

Our package also provides clinicians and researchers with a choice of BA packages; for example, the Reynolds package (2020) is used at present with young people with mild to moderate depression in schools, whereas ours was designed to young people with more severe depression attending specialist CAMHS out-patient services.

Thus, our first aim was to co-develop with young people and clinicians our BA programme for use in specialist CAMHS and develop a training programme for relatively inexperienced clinicians such as assistant psychologists or newly qualified nurses. Our second aim was to conduct an open feasibility mixed methods study with further development of the training programme including a website, training videos, and a fidelity measure. At the time of the studies, researchers had not developed a fidelity measure though a new fidelity measure for the Reynolds package (2020) has been developed recently (Hodgson, 2020).

Two qualitative studies of clinicians' experiences of implementation, beliefs and attitudes about BA, and young peoples' experiences of BA are reported elsewhere.

Phase one: Workbook development

BD and SM reviewed the available adult BA workbooks at the time of development in 2014 (e.g. (Lejuez et al., 2011). The intervention developed spans eight sessions based on clinical experience, and the growing evidence that young people do not stay in therapy for depression longer than about 8 sessions. (Goodyer et al., 2017). There is

also evidence that the optimal number of sessions may be fewer than that reported in the adult literature (O'Keeffe, et al., 2019a).

The eight workbooks (figure A), each have a title page, overview, session agenda, symptom and risk check, homework review, session content, session summary (feedback and goals review) and a parent information sheet. The first four sessions focus on socialisation to the model, goals and values, and activity scheduling. The following three address avoidance and overcoming barriers to activation. A final session covers planning for relapse-prevention.

Figure A: insert here

The different components were developed over a 12-month period. SM initially showed the workbooks and took verbal feedback from volunteer young people and parents who had attended the service. The workbooks were then used with a convenience sample of young people from SM's clinical case load. Feedback was collected verbally and from feedback questionnaires developed for the project, using Likert scale ratings and free text questions.

Once the workbooks were developed, a one-day training workshop was delivered by SM and BD and a supervising clinical psychologist. We trained four junior clinicians, who then used the workbooks in three specialist CAMHS in Lancashire. Additional feedback from clinicians was used to further develop a clinician's guide to the

workbooks. We recruited 15 adolescents aged 11-17, referred to CAMHS with low mood who self-scored 27 or more on the long form (child rated) version of the Mood and Feelings Questionnaire (MFQ) (Wood et al., 1995).

For both phase one and phase two studies, we used the same inclusion and exclusion criteria. We excluded those with substance addiction, anorexia nervosa, psychosis and those who had already completed a course of psychological therapy. We included all others, including those with complex presentations, co-morbidity and young people presenting with self-harm, if risk was deemed manageable by the out-patient team.

Ethical approval for phase one was granted by the National Research Ethics Service Committee North West, in March 2015 (REC reference: 15/NW/0155).
Ethical approval for phase two was from the same committee in February 2019 (REC reference: 19/NW/0042). Written consent was obtained from young people and parents.

Phase two: Mixed method feasibility study

The second phase was a feasibility study over 10 months (July 2019 to April 2020). This study was initially planned to take place in two sites in east Manchester (Oldham and Tameside) UK, although due to loss of staff and service differences, recruitment largely took place in Oldham. Inclusion and exclusion criteria were the same as for phase one. We developed the training programme further to include a fidelity measure, video training materials, digital versions of the 8 workbooks and a website

delivery platform for staff and young people. When covid-19 started towards the end of this study, we adapted the website further for clinicians to use with young people over the phone or via video calls. Our training videos were developed at the request of trainees and provide a standardised introduction into how to start conversations about key BA ingredients. We complemented these with worked vignettes within the training manual.

Outcome Measures

For phase one the main outcomes were feasibility (recruitment rate and retention), and acceptability of the BA programme for young people and clinicians. Acceptability of the workbooks and the programme was assessed using specific questionnaires after every session, with likert style questions (rated 1 to 5, 5 being high acceptability) and free text questions from both young people and clinicians. Ratings for the overall programme were collected at the end of treatment in a similar format.

For phase two, our outcome measures were changes in depressed mood (Mood and Feeling Questionnaire, self-rated long form version (MFQ)), (Costello & Angold, 1988) and impairment (Clinician Global Assessment Scale, CGAS) (Shaffer et al., 1983), as well as feasibility of recruitment and retention.

Results: Phase one

Over one year (2015), 15 young people took part, mean age of 14.6 (range 13 to 16). The 2 males and 13 females who participated had a range of co-morbidities. 9 had anxiety, 2 had social communication problems, 2 had gender dysphoria, 1 had learning problems, 1 had auditory hallucinations. 6 were receiving Selective Serotonin Re-

uptake Inhibitor (SSRI) medication. The young peoples' mean MFQ at baseline was 41.5 (sd 8.8) indicating moderate to severe depression and their CGAS was 57.1 (sd 11.6), indicating noticeable problems of impairment.

The acceptability of the workbooks was good or very good (4 or 5s on a 5-point likert scale) from both the young people and clinicians. Acceptability for the BA programme overall was also either 3 or 4 ('OK' or 'good'). Free text comments gave suggestions about areas for improvement, and we adjusted the workbooks, as well as the clinicians guide. Full detail of feedback is available in the supplementary file. Although not a primary aim of the study, 6 of the 15 young people completed all 8 sessions with 10 completing at least 4 sessions. Perceived mood improved for 9 of the 15 young people.

Results: Phase two

Figure B shows the flow of young people through the study and the number of sessions and questionnaires completed. We used convenience sampling and depended on the referral teams and initial assessment teams to refer young people to the study. We did not have research resources to screen all young people with low mood, nor was this a routine process in the clinical services. 36 consented to the study, of which 33 started BA therapy and 27 completed 4 or more sessions. The mean number of sessions completed was 6.6, with a median of 8.

Insert figure B here

Table one shows the characteristics of young people, their MFQ and CGAS scores at baseline and after BA therapy. Paired t tests were calculated and showed significant change on MFQ and CGAS between baseline and after therapy.

Table one here

From the young people's case note narratives, 20 presented with low or minimal risk of suicidal thoughts or self-harm, 9 with moderate or high risk. Risk decreased in 6 and continued in 3 throughout therapy.

16 young people were discharged from the service. 3 were discharged after failing to engage with any part of the service (the did not commence BA, despite consenting to do so). 1 was discharged after dropping out after 2 sessions of BA, attempts to follow up failed, outcome was unknown. The remaining 12 were discharged with improvement in functioning and mood. For the other 20, most were referred to other parts of CAMHS, though 2 were referred to external services (adult Attention Deficit Hyperactive Disorder (ADHD) service, and Early Intervention Service for Psychosis). Internal referrals included 2 for Autism Spectrum Disorder (ASD) assessment, 2 for anxiety work, 1 to the eating disorder service, 3 for attachment/psychotherapy work, 1 for trauma focused work, 4 for medication review, 1 for family therapy, and the other 4 for general review.

Clinical outcomes showed 25 as improved (CGAS improved by 10 or more points with a case note narrative confirming improvement). Of those that had not improved, 2 were discharged due to non-engagement, the other 9 continued to be assessed or offered further treatment.

Fidelity measure

The fidelity measure was developed by AM, SB, JH, LK and BD, and adapted (with permission) from a measure used in the BEAT-IT RCT trial (Jahoda et al., 2017). Our measure covers similar areas; process and content. Process sections, (e.g. a collaborative stance, scaffolding sessions, showing warmth and empathy), consisted of 9 items overall; 6 focused on structure and flow of therapy, 2 sections on communication, and 1 on empathy. Each section is rated on a four point scale with anchored descriptions.

The content sections contain items specific for each workbook with binary ratings for each question. There is also a general content section that pertains to all sessions.

Of a total of 219 sessions over the course of the study, we rated 16 sessions (7%) from 5 therapists to assess adherence to the BA manual and ensure parity and consistency across therapists. We only collected tapes during the student MsC study (July to October 2019). Of the 16 sessions rated, 8 were from session one, 2 from session two, 1 from session three, 2 from session four, and 3 from session six. SB and AM rated each session independently to assess inter-rater reliability. The internal consistency of the process section, measured by Cronbach alpha, was 0.86. Agreement between raters for the process sections was high overall, except for one item “asking for

feedback within current session". With this item removed agreement between raters was 93%.

Clinician adherence on both process and content measures was high and consistent across the different sessions rated. Out of a total score of 36 for the 9 process measures, the mean score was 32.3 (sd 3.3). For content, the adherence was 96% for session one, 100% for session two, three, and four, and 83% for session six. More detail about the fidelity measure is available in the supplementary file.

Training and Supervision

We delivered training for clinicians and supervisors in the phase two feasibility study over one and a half days, and then offered half day follow up training sessions to the clinicians every three months. These half day sessions included specific case discussion and general clinical dilemma discussions, particularly dealing with risk, complexity, and co-morbidity. Usual clinical supervision for the therapy and case management was offered fortnightly by the local clinical supervisors.

Qualitative findings

9 young people and 9 staff were interviewed about their experiences of BA and implementation (staff). The methodology, analysis, and results are reported separately (Whittenbury et al, 2020; Shenton et al, 2020).

Covid-19 experience and adjustments

During the latter part of the study, we adapted BA delivery because of the covid-19 pandemic. We improved our website, so that staff and young people could view and

download the workbooks, and complete them digitally if they chose to do so. 5 young people completed BA during covid-19 pandemic using this blended approach.

Discussion

Our BA programme and workbooks were co-produced with young people and clinicians over a 6-year period. The two studies in specialist CAMHS suggest that BA can be used safely, improve mood, and be used by relatively inexperienced staff. The YP who took part had moderate to severe depression, many with co-morbid conditions, risk and complexity. Outcomes after therapy from the second study are in line with published RCTs of psychological therapies (Goodyer et al., 2017; Goodyer et al., 2008). Other researchers using BA in specialist CAMHS have found similar results (Gudmundsen et al., 2016; Kitchen et al., 2020; Pass et al., 2018).

Our retention rate in both phase one and two studies was in line with other studies such as the IMPACT trial where 37% did not complete all sessions (O'Keeffe, Martin, Goodyer, et al., 2019a).

Our training programme requires further development including a competency assessment (Puspitasari et al., 2017), though the findings from the fidelity measure development suggest that competency was achieved in the second phase. We felt that the fidelity scale helped clinicians focus on key essential ingredients of BA, as well as open a discussion of the need to be flexible and attentive to therapeutic process.

BA is being integrated into UK services such as the Improving Access to Psychological Therapies services (adult and child, IAPT and CY-IAPT), and NICE (2019) have

recommended further research in BA for young people with mild depression. IPT-A incorporates some aspects of BA, and briefer adapted versions of IPT-A show promise for mild to moderate depression delivered by youth workers (Wilkinson et al., 2018). We believe BA has a place for young people with more severe depression, and for young people with comorbidity and risk issues. Findings from adult studies suggest this (Lorenzo-Luaces & Dobson, 2019), and if this was true for young people, then BA could be offered as a first-line treatment in specialist services. This might help free up resources for those young people who need more specialised therapy.

Our BA programme, designed for clinical and research use in a specialist CAMHS context, adds to the two other manualised BA programmes (McCauley et al., 2016; Reynolds, Pass & Pimas, 2020). We believe our package offers some potential advantages, particularly the use of workbooks to deliver BA. The workbooks provide a clear structure for less experienced clinicians, and our training programme was also designed specifically for working within specialist CAMHS and with young people with more severe and complex problems. We were keen to train professionals to be flexible in the use of workbooks and the order in which they were used, particularly if there were considerable barriers to activation. We feel flexibility is essential to BA, and needs further consideration. For example, in research with adults, using BA may have more impact for adults with depression, and other strategies more utility for when anxiety symptoms predominate (Webb et al., 2016). For supervisors of BA and CBT therapy, there is often tension about where to focus; cognitions, behaviour or both. Researchers too vary in their focus (Bailey, 2014) and within BA itself, there is on-going discussion about the importance of whether a focus on values rather than goals (Stein

et al., 2020), with recommendation for more research in this area. Interviewing BA therapists (Cassar et al., 2016), highlights areas that therapists regard as important; a focus on values, barriers and activity in producing change. Qualitative research with young people shows that therapeutic process is also important in therapeutic change and retention within therapy (O'Keeffe, Martin & Midgley, 2020; O'Keeffe et al., 2020; O'Keeffe, Martin, Target, et al., 2019b).

The Covid 19 pandemic pushed our research study into developing blended BA therapy including adapting our BA website to facilitate clinical work. Clinician reports (RCPsych digital survey 2020, in submission), suggest that some initial face-to-face meetings are needed with young people and their families to developing a working relationship and assess risk. This can then be followed by choices of blended approaches facilitated by digital platforms.

Limitations

The small sample size, open and uncontrolled design of both phase one and two studies, together with limited outcome measures limit the findings of our work. In addition, one site was more successful in recruiting young people to the study and having staff available to deliver BA therapy. This was due in part to high staff turnover and resource pressures on other parts of the service, and also that less specialist therapy was available in the site that was more successful with recruitment. Less availability of specialised therapy seemed to promote a more positive attitude to BA in the more successful recruitment site.

We did not follow up the young people over a longer time period, and larger funded randomised controlled trials are needed including long-term follow up and economic analysis. Although our phase two study suggests effectiveness of BA for young people with more severe depression, we need better evidence than this study provides. It may be that BA is no better than general support (Weisz et al., 2017), though evidenced based approaches probably have additional impact (Deighton et al., 2016).

Conclusion

BA has the potential to offer an evidenced based personalised first-line treatment for young people who have all levels of depression severity and complexity. BA may be deliverable at a more affordable cost in terms of training time and clinician experience level, so freeing up resources for more specialist intensive therapies within specialist CAMHS.

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Contributorships

Dr Bernadka Dubicka was chief investigator for the projects and co-produced the manual, fidelity measure and paper. Dr Susanne Marwedel co-produced the workbooks and led the phase 1 study. Sabah Banares co-developed the fidelity measure. Dr Amy McCulloch co-developed the fidelity measure, the professionals' manual and video materials. Dr Taghrid Tahoun co-developed the professionals' manual. Dr Jasmine Hearn provided academic support on the methodology and supervision for Sabah Banares and co-wrote the paper. Dr Leo Kroll was principle investigator for the second project, co- developed the professionals' manual, website, videos, and fidelity measure. He led on analysis and writing the paper.

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All authors listed meet the authorship criteria according to the latest guidelines of the International Committee of Medical Journal Editors, and all authors are in agreement with the manuscript.

Conflict of interests

BD receives funding from the National Institute of Heath Research HTA programme.

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Table one: Characteristics and outcomes phase two feasibility study

Age	
Mean	14.5, range 12-17 (sd 1.2)
Gender	
Male	11(33%)
Female	22(67%)
Ethnicity	Mixed (White and Asian) (2), Asian (2), Black (African) (1), White British (28)
Co-morbidities (one or more)	
	19/33 (58%) had at least one anxiety (12), social communication difficulties (3), gender dysphoria (1), adhd (1), eating problems (1) and auditory hallucinations (1), medical problems (4), trauma (3), OCD (1)
Medication	
Anti-depressants	4/33
Other psychotropic medication	None
Questionnaire scores, pre and post	
MFQ baseline	Mean 43.2 (sd 9.3) n=36
MFQ post treatment	Mean 27.6 (sd 14.7) n=28
Difference with 95% confidence intervals (paired t)	14.6 (8.7 to 20.2) n=28
CGAS baseline	Mean 52.3 (sd 17.8) n=33
CGAS post treatment	Mean 69.8 (sd 13.7) n=29
Difference with 95% confidence intervals (paired t)	18.0 (11.9 to 24.2) n=29

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