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Tackling chronic depression, adapting and testing the DIALOG+ solution-focused approach for people with long-term depression: the TACK mixed-methods research programme

Victoria Bird, Philip McNamee, Neil Walker, Yan Feng, Mustapha Mohammed, Esubalew Assefa, Aleksandra Matanov, Lauren Jerome, Andrew Molodynski, Shonagh Scott, Latha Guruvaiah, John Geddes, Sue Collinson, Rose McCabe and Stefan Priebe

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Extended Research Article

Tackling chronic depression, adapting and testing the DIALOG+ solution-focused approach for people with long-term depression: the TACK mixed-methods research programme

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Abstract

Background: Long-term (previously termed chronic) depression is associated with significant personal, social and economic consequences often resulting in a poor quality of life for individuals. Effective treatments that improve quality of life for individuals with chronic depression remain limited. DIALOG+, a solution-focused and person-centred intervention, guided by a tablet-based application, was developed to address these challenges. Initially proven to be effective in handling psychotic disorders, this study adapted and evaluated DIALOG+ for individuals with chronic depression.

Objectives: The research aimed to adapt and assess the feasibility, clinical and cost-effectiveness of DIALOG+ for improving quality of life, reducing depression severity and enhancing treatment satisfaction among individuals with chronic depression.

Setting: The study was conducted across nine National Health Service sites in England, encompassing both urban and rural settings. Participants were recruited from outpatient Community Mental Health Teams, including primary care services, such as increasing access to psychological therapies, ensuring diverse sociodemographic characteristics and clinical contexts. Clinicians from varied professional backgrounds, including mental health nurses, psychiatrists and social workers, were trained to deliver the intervention.

Design: The study comprised multiple interlinked work packages:

1. Systematic review: existing recruitment and retention strategies for trials with individuals with depression.
2. Focus groups and pilot study: to adapt the intervention.
3. Small-scale cluster randomised controlled trial: testing feasibility of the intervention and trial processes.
4. Large multisite pragmatic cluster randomised controlled trial: including a nested qualitative process evaluation and economic evaluation.
5. Training and implementation study: evaluating feasibility and applicability within different clinical services.

A total of 366 participants with chronic depression were included. Patients were clustered by clinician and clusters randomised 1 : 1 to receive DIALOG+ or an active control (treatment as usual with DIALOG scale completion). Participants were assessed at baseline, 3, 6 and 12 months. The primary outcome was subjective quality of life, measured by the Manchester Short Assessment of Quality of Life at 12 months. Secondary outcomes included depression severity (Montgomery–Åsberg Depression Rating Scale, Beck Depression Inventory-II), treatment satisfaction (Client Satisfaction Questionnaire-8) and health-related quality of life (EuroQol-5 Dimensions, five-level version). Economic evaluation was conducted from National Health Service and Personal Social Services perspectives. Process evaluation involved implementation data and interviews with participants and clinicians to assess intervention experience.

Results: The systematic review highlighted the overall poor quality of reporting for existing trials of psychosocial intervention, with many trials failing to outline information on recruitment and retention. It was demonstrated that the intervention was feasible and acceptable to individuals with chronic depression during the feasibility and pilot work. Although the intervention remained unchanged, feedback from the initial phases of the project, alongside lived experience input led to changes in intervention training, which included the addition of case vignettes specific to long-term depression. Within the cluster randomised controlled trial, at 12 months, the DIALOG+ group exhibited a borderline significant improvement in Manchester Short Assessment of Quality of Life scores compared to the control group (adjusted mean difference: 0.18, $p = 0.05$). This equated to an average improvement of 1 point on 2 of the 12 Manchester Short Assessment of Quality of Life domains. There were no significant differences in any other outcome at 6 and 12 months. However, longitudinal analysis demonstrated significant reductions in Montgomery–Åsberg Depression Rating Scale and Beck Depression Inventory-II scores in the DIALOG+ group at 12 months ($p < 0.01$), and participants reported better coping strategies and resilience in managing depressive symptoms. The intervention was associated with an incremental cost-effectiveness ratio of £4749 per quality-adjusted life-year gained. Probabilities of cost-effectiveness were 79.8% at a willingness-to-pay threshold of £20,000/quality-adjusted life-year and 87% at £30,000/quality-adjusted life-year.

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Despite high retention rates (73% at 12 months), challenges included attrition due to COVID-19 disruptions, with whole clusters lost during early lockdown phases. Fidelity to the intervention protocol varied, with just under a third of participants receiving fewer than three sessions (the minimum recommended dose). Nonetheless, the observed treatment effects were robust across varying levels of engagement.

Findings from the process evaluation were increased satisfaction with care, improved therapeutic relationships and a greater sense of empowerment. However, some participants noted challenges with the structured nature of the intervention and the use of technology. This was mirrored by the clinician experience, which found DIALOG+ easy to integrate into routine care and appreciated its structured, patient-centred approach. Barriers included variability in implementation fidelity and technological challenges, particularly during remote delivery.

Limitations: Key challenges across the programme included: (1) disruption from the COVID-19 pandemic, leading to adaptations in delivery methods and pauses in recruitment; (2) implementation variability, with some clinicians requiring additional training to maintain fidelity within the cluster randomised controlled trial; and (3) attrition and missing data, particularly in measures for economic evaluation, which necessitated the use of multiple imputation for some analyses.

Conclusions: The DIALOG+ demonstrated small but clinically meaningful improvements in quality of life and reductions in depression severity for individuals with chronic depression. While the improvement in Manchester Short Assessment of Quality of Life scores was very modest, it represents a potential gain for a population with long-term difficulties and low baseline quality of life. The probabilities of the intervention being cost-effective in comparison to active control at the National Institute for Health and Care Excellence recommended willingness-to-pay thresholds were high. The intervention was also associated with high patient and clinician satisfaction. These findings support the wider implementation of DIALOG+ in routine mental health care, with adaptations for remote delivery and ongoing support for clinicians.

Future directions: Further research is needed to explore the long-term impacts of DIALOG+ on quality of life and depression severity. Peer-delivered models and strategies to enhance engagement with the intervention may strengthen its effectiveness and scalability.

Trial registration: This trial is registered as ISRCTN16864442. The definitive cRCT was registered as ISRCTN11301686.

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List of abbreviations

BDI-II	Beck Depression Inventory
BEH	Barnet, Enfield and Haringey Mental Health NHS Trust
CEAC	cost-effectiveness acceptability curve
CMHT	Community Mental Health Team
CONSORT	Consolidated Standards of Reporting Trials
cRCT	cluster randomised controlled trial
CSQ-8	Client Satisfaction Questionnaire-8
CSRI	Client Service Receipt Inventory
ELFT	East London NHS Foundation Trust
EPOS	European Prediction of Psychosis Study
EPUT	Essex Partnership University NHS Foundation Trust
EQ-5D-5L	EuroQol-5 Dimensions, five-level version
ICC	intracluster correlation coefficient
ICECAP-A	ICEpop CAPability measure for Adults
ICER	incremental cost-effectiveness ratio
LEAP	Lived Experience Advisory Panel
MADRS	Montgomery–Åsberg Depression Rating Scale
MANSA	Manchester short assessment of quality of life
NICE	National Institute for Health and Care Excellence
PCTU	Pragmatic Clinical Trials Unit
PPI	patient and public involvement
PSS	Personal Social Services
QALY	quality-adjusted life-year
QoL	quality of life
RCT	randomised controlled trial
SAE	serious adverse event
SEM	structural equation modelling
SMI	serious mental illness
SOP	standard operating procedure
SQoL	subjective quality of life
TACK	TACKling chronic depression
TAU	treatment as usual
WASP	World Association of Social Psychiatry
WP	work package
WTP	willingness to pay
YFC	years of full capability

Plain language summary

A common mental illness is 'chronic depression', which involves long-lasting low mood. Around one in four people who experience depression go on to be diagnosed with chronic depression. People with chronic depression are treated by a range of teams, where they have regular one-to-one meetings with a mental health professional. A solution-focused intervention called 'DIALOG+', which structures communication within these meetings improved quality of life, reduced symptoms and saved the National Health Service money when used with people with another serious mental illness called psychosis. The research team were interested to discover if using DIALOG+ with people with chronic depression would have the same benefits.

This programme involved six studies which aimed to adapt and test DIALOG+ for people with chronic depression. Throughout, it was important to include the perspectives of individuals with lived experience of chronic depression, so we set up a Lived Experience Advisory Panel.

First, we did some small-scale testing with the original DIALOG+ to see what changes might be needed. Findings indicated that the same life areas and treatment aspects were relevant. This meant that very little needed to be changed about the intervention. However, the training for mental health professionals needed adapting. This led to a feasibility trial, which tested the trial processes in preparation for a large randomised controlled trial.

Finally, a randomised controlled trial was conducted, which involved 356 people with chronic depression across multiple National Health Service sites in England. We found that receiving DIALOG+ over 12 months marginally improved the quality of life compared to a comparison group. This means that people who received DIALOG+ were more satisfied with their life than people who did not receive the intervention. We analysed how much it costs to deliver DIALOG+ and found that, although DIALOG+ was slightly more expensive, these costs were minimal.

The experiences of service users and clinicians using DIALOG+ were largely positive, and many wanted to continue using DIALOG+. Further research is needed to look at how DIALOG+ works over a longer period of time when used in the National Health Service. Research could also look further into the reasons why some health professional and patients did not want to use DIALOG+ or only used it for a short period of time. However, taken together, this shows that DIALOG+ is a worthwhile approach to use for people with chronic depression across different settings in the National Health Service.

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Scientific summary

Background

Depression is one of the most common serious mental disorders globally. There is widespread recognition of the negative impact it can cause not only to affected individuals but also on healthcare systems and wider society. Despite the advances in and improved availability of treatments over the last few decades, depression continues to be prevalent within the general population. A substantial proportion of people who experience an acute episode of depression go on to develop a chronic disorder, with many experiencing recurrences or long illness periods throughout their lives. It has been estimated that 20–30% of individuals diagnosed with major depressive disorder, and up to 47% of those treated in mental healthcare services, suffer from chronic-recurrent forms. Long-term or chronic depressive disorders are associated with poorer clinical and social outcomes, including more severe depressive episodes, an increased suicide risk, physical comorbidity, reduced social networks and significant functional impairment.

The available evidence rarely distinguishes between initial onset and chronic-recurrent forms, with a resulting lack of understanding of which therapeutic models are most effective, or appropriate, for long-term forms of depression. Additionally, psychotherapeutic approaches are often expensive and require referrals to specialist services or professionals. There is a need, therefore, to develop and adapt evidence-based interventions that can be implemented across different clinical settings to make routine care for people with chronic depression more effective and accessible.

The DIALOG+, a technology-assisted and resource-oriented intervention, might be one potential solution. The intervention is supported by an app and is based on the principles of quality-of-life (QoL) research, patient-centred communication and solution-focused therapy. It was purposefully developed to be flexible in delivery and applicable to a variety of settings. The aim of DIALOG+ is to improve clinical outcomes through the use of routine meetings with mental health professionals by facilitating more structured conversations based on the therapeutic principles of solution-focused therapy. The intervention asks individuals to complete a structured QoL scale called the DIALOG scale. This includes 11 items, 8 related to overall subjective QoL and 3 with treatment satisfaction. The items are rated from 1 to 7 on a Likert scale. The DIALOG scale is loosely based on the Manchester short assessment of quality of life (MANSA), but it includes a different number of items and different scoring scale. Crucially following each item on the DIALOG scale, the patient is asked whether they would like help with the area. Following an overview of the 11 items, up to 3 are selected to take forward in the remainder of the consultation. A four-step brief solution-focused approach is then applied to help identify the patient's resources and what actions can be taken to address the concerns raised in the DIALOG scale.

The DIALOG+ has been shown to be effective for service users with psychosis receiving treatment within the NHS. A cluster randomised controlled trial (cRCT), of DIALOG+, compared to an active control, demonstrated that regular use resulted in better subjective quality of life (SQoL), better social outcomes as well as lower treatment costs (£1500 per person) over a period of 1 year.

The TACKling chronic depression (TACK) programme aimed to assess whether similar benefits could be established for service users with long-term depression when using DIALOG+.

Objectives

The overall objective of the TACK programme was to adapt DIALOG+ for service users with long-term depression and then test the adapted intervention to evaluate clinical effectiveness and cost-effectiveness. This was undertaken across six inter-related work packages (WP), with each WP having its own key objective.

Work package 1 (systematic review) aimed to synthesise existing knowledge regarding successful recruitment and retention into depression trials. The objectives were to: (1) identify factors which facilitate or impede recruitment and

retention of participants into trials investigating psychosocial interventions for depression and (2) identify previous strategies that have successfully improved recruitment and retention into such trials.

Work package 2 (exploratory study) aimed to establish the applicability of the existing DIALOG+ software/intervention and had three specific aims: (1) to explore the perspective of different stakeholders in relation to the existing DIALOG+ intervention and identify required adaptations for long-term depression; (2) to exploratorily test the adapted intervention with 5 clinicians and 15 patients, in situ; and (3) to adapt existing online training materials.

Work package 3 (feasibility trial) aimed to establish the feasibility of conducting a large-scale trial and had defined feasibility objectives. These were to: (1) assess the feasibility of recruitment and retention strategies from Community Mental Health Teams (CMHTs) and additional NHS services that treat service users with long-term depression; (2) assess the feasibility of the proposed eligibility criteria; (3) assess the feasibility of the selected outcome measures and (4) assess the acceptability of the adapted DIALOG+ intervention for this patient population.

Work package 4 (definitive cRCT) had a primary objective to establish whether the use of DIALOG+ over a 12-month period, in various clinical settings, could improve QoL in patients with long-term depression, compared with an active control. Secondary objectives were to evaluate whether DIALOG+ improves secondary clinical outcomes and assess the cost-effectiveness of the intervention.

Work package 5 aimed to further understand the trial findings through a mixed-method, embedded process evaluation focusing on the experience of delivery or receiving the intervention, and implementation barriers and facilitators at different levels (individual, team and organisation).

Work package 6 aimed to trial the developed DIALOG+ training materials with non-CMHT staff to assess the feasibility and applicability of the training across different clinical settings where individuals with depression may access care.

Methods

The TACK WPs used a variety of methods, collecting both quantitative and qualitative data, to address the research objectives.

Work package 1 comprised a systematic review and narrative synthesis. Papers were identified and extracted from the reference list of the draft National Institute for Health and Care Excellence (NICE) guidelines for the management of depression, published in 2017. Two reviewers independently screened the list of papers and decided upon included papers before key data were extracted. Findings from included papers were narratively synthesised to generate findings.

Work package 2 was an exploratory pilot utilising qualitative methods to test the original DIALOG+ software in different clinical settings to establish its applicability and relevance to service users with long-term depression. DIALOG+ was tested in a convenience sample in routine community care appointments for 3 months across three different NHS Trusts in England. Of these, 15 clinicians and 19 service users were individually interviewed about their experiences. Thematic analysis was used to analyse the interview transcripts by an analytic team which included a service-user researcher.

Work package 3 was a mixed-methods feasibility study involving a two-arm cRCT and a qualitative evaluation. It was conducted in three CMHTs in South-East England. Eligible participants, and their clinicians, were cluster-randomised to either the intervention (DIALOG+) or an active control group [treatment as usual (TAU) + completion of the DIALOG scale with no clinical input]. Participants were assessed at baseline and 6 months post randomisation. Qualitative interviews were conducted with the participants from the DIALOG+ arm about experiences of receiving and/or delivering the intervention.

Work package 4 was a large-scale, multisite two-arm cRCT, that was hosted in nine NHS sites across England. Eligible participants were identified by their treating clinician and screened by a researcher. Once randomised, all participants within the same cluster (clinician acted as the unit of randomisation) received regular sessions of DIALOG+ over a

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12-month intervention period. The active control arm used the DIALOG scale at the end of their routine sessions. Participants completed outcome measures at baseline, 3, 6 and 12 months post randomisation, facilitated by blinded researchers. Primary outcome was SQoL as measured by the MANSA at 12 months.

Work package 5 used a mix of quantitative and qualitative methods as part of the process evaluation. One-to-one qualitative interviews were conducted with trial-arm service-user participants who were purposively sampled based on key criteria. Additionally, routine (clinical) DIALOG+ data that were collected during intervention delivery were extracted from the trial tablets and analysed descriptively. Finally, audio and video recordings of DIALOG+ being delivered were analysed to check for clinician fidelity to the therapeutic manual.

Work package 6 piloted the use of the DIALOG+ training package across different services. Post-training surveys and in-depth qualitative interviews were used to explore views about the training delivered and any additional needs. Survey data were analysed descriptively, and framework analysis was used to generate findings from interview transcripts.

Results

The systematic review synthesised data from 90 manuscripts. Publication dates ranged from 1996 to 2016, and studies came from 17 different countries. Findings were very mixed, highlighting that equal numbers of included studies either over or under-recruited individuals within their trials. Few studies offered incentives to increase participation, and the modality of delivery of the intervention seemed to have a small but significant impact on retention. Recruiting directly from mental health services was the most popular approach, compared to allowing self-referral, but the impact on retention was unclear. The overall quality of depression trials was low, and the reporting of recruitment and retention strategies was poor despite the Consolidated Standards of Reporting Trials statements.

For WP2, the analysis indicated that DIALOG+ was viewed as acceptable by both service users with long-term depression and their clinicians, albeit with some caveats. Clinician training required significant improvements to address perceived issues, particularly around support with using technology and integration of DIALOG+ into their working practices. The content of the intervention itself needed no adaptation and was found to be directly applicable to the patient population.

For WP3, 36 service users and 11 clinicians were cluster-randomised into the trial. This represented a 75% recruitment rate, explained by organisational-level difficulties at one potential trial site. Eligibility criteria were therefore modified ahead of the definitive trial launch to ensure adequate inclusiveness and reflection of the clinical reality relating to the treatment of long-term depression. The selected outcome measures were feasible except for the clinician-rated ones, which were replaced in the main trial case report form. There was a trend towards better SQoL and a decrease in depressive symptoms at 6 months in the intervention arm. Qualitative interviews were conducted with seven service users and six clinicians, with data indicating that DIALOG+ was highly acceptable to those that used it.

Within WP4, n = 366 service-user participants were recruited to the trial, representing a 97.3% recruitment rate, with a 7.4% screening failure rate. One hundred and twenty-eight clusters were randomised, with an average cluster size of 2.9, ranging from −1 to 6. The primary outcome was assessed in 79% of the sample at 3 months, 76.5% at 6 months and 73.4% at 12 months. The difference between groups on the primary outcome (MANSA score at 12 months) was significant at p = 0.05, with the direction of effect indicating an average improvement in MANSA-assessed QoL by one point on approximately 2–3 of the 12 composite questions. No statistically significant effects were observed for SQoL at 3 and 6 months, nor any of the other secondary outcomes at any time point. The longitudinal analysis indicated a significant but small positive effect for the intervention compared to the active control at all time points.

The majority of participants were satisfied with their treatment while using DIALOG+, with 78% of respondents saying they were a little or totally satisfied with their care after 6 months. When asked, at 12 months, if they preferred DIALOG+ to the treatment they had received previously, 85% had either no preference or preferred DIALOG+.

Economic evaluations showed that the overall costs involved in providing the intervention arm were relatively low (£16.86 per participant in the DIALOG+ arm vs. £12 per participant in the active control arm). Base-case analysis suggested that DIALOG+ is more effective over the 12-month trial period than TAU, justifying the marginally increased costs. The probabilities of DIALOG+ being cost-effective in comparison to TAU were high at the NICE-recommended willingness-to-pay thresholds [79.8% at £20,000/quality-adjusted life-year (QALY) and 87% at £30,000/QALY].

Within WP5, 43 service users and 25 clinicians were interviewed. Analysis of data resulted in six themes that described the derived and experienced benefits of using DIALOG+; these were: (1) structure and focus; (2) getting a bigger picture; (3) mapping the recovery journey; (4) focusing on strengths; (5) working on solutions and (6) the impact on therapeutic relationship. Regarding the extracted DIALOG+ data, in total, there were 496 individual DIALOG+ sessions recorded. Number of sessions delivered per participant ranged from 1 to 12, with the mean number of sessions being 3.64; 49.2% of included patient participants had between three and six sessions, representing an adequate intervention dose. Participants rated their mental health as the lowest life domain (mean score = 3.45), and relatedly, the most frequent request for additional help was with their mental health (in 62.7% of sessions). Fidelity checks were completed on six observational recordings and resulted in generally high adherence scores, showing that clinicians, in general, tended to be able to apply the therapeutic principles they were taught in training. The global adherence score ranged from 13 to 17 (out of a possible total of 20).

In total, 86 clinicians responded to the post-training survey in WP6. Overall, clinicians found the training to be sufficient, with 90.7% of respondents agreeing or strongly agreeing that the training seminar met its stated aims and objectives. However, confidence was lacking in using the DIALOG+ app, with only 69.8% agreeing that they felt confident using the technology, and only 66.3% either agreeing or strongly agreeing that they felt confident in delivering DIALOG+ to their caseload.

Fourteen clinicians agreed to be interviewed following their attendance at training and the application of DIALOG+ as part of their clinical roles. The success of the training session was linked to several elements, primarily the relevance of the training content to their specific service setting, coattendees and the skill of the training facilitator. Factors to improve training were most often related to technical aspects of using the technology. Overall, clinicians from non-CMHT settings were content with the generic training they received and felt it was applicable to their routine practice.

Conclusions

The combined findings of the TACK programme demonstrate that DIALOG+ is a feasible and effective intervention for use with people with long-term depression in community care and other clinical contexts. Although the effect between DIALOG+ and DIALOG observed in the present study were small, this merged with the findings of the other definitive cluster RCT (cRCT) testing DIALOG+ for people with psychotic disorders [European Prediction of Psychosis Study (EPOS)], which suggests that DIALOG+ can be used as a generic, care planning tool across a range of serious mental illnesses. Prior to the programme, the evidence base for use of DIALOG+ was restricted to service users with psychotic disorders, there are now two large definitive trials with positive results, demonstrating that DIALOG+ can improve QoL for service users with a range of mental health symptoms and disorders. This is encouraging for services such as CMHTs who treat diagnostically heterogeneous populations and often need tools and resources that need to be applied across a diverse range of presentations.

Findings from the training study, however, suggested that more development work is needed to ensure that clinical training in DIALOG+ is reflective of the realities and specificities encountered by individual clinicians or teams. Although the current general training resources are adequate, some elements of the training, such as clinical vignettes, are required to be context-specific. Future research should also investigate how ongoing supervision can support the implementation of DIALOG+ and which training models lead to the highest fidelity and highest patient satisfaction.

Finally, in-depth economic evaluation showed that the costs involved in the delivery of DIALOG+ were relatively low, both in absolute terms and in comparison to the control arm. DIALOG+ has high probabilities of being cost-effective compared to active control from both the NHS and Personal Social Services perspectives and the societal perspective.

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Therefore, DIALOG+ may be a clinically effective and cost-effective intervention for people with chronic depression (including those with complex presentations), which is relatively simple to use and integrate into exiting systems and practices within the NHS.

Future research should focus on how DIALOG+ can be sustainably implemented and embedded within mental health services, including integration within established electronic patient record systems. Such research could be completed through naturalistic experiments or ethnographic observational methods, considering that DIALOG+ is increasingly used within select NHS Trusts.

Trial registration

This trial is registered as ISRCTN16864442. The definitive cRCT was registered as ISRCTN11301686.

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Synopsis

The TACKling chronic depression (TACK) programme of applied research comprised six interlinked work packages (WPs), with the overall aim of improving quality of life (QoL) for people with chronic depression (as shown in *Figure 1*). The specific objective was to adapt and evaluate the clinical and cost-effectiveness of a novel solution-focused intervention, DIALOG+, for this population. The findings of this programme have been separated into six sections below, which map onto the six WPs. Each section gives a brief overview of the aims and objectives, methods, main findings and conclusions drawn.

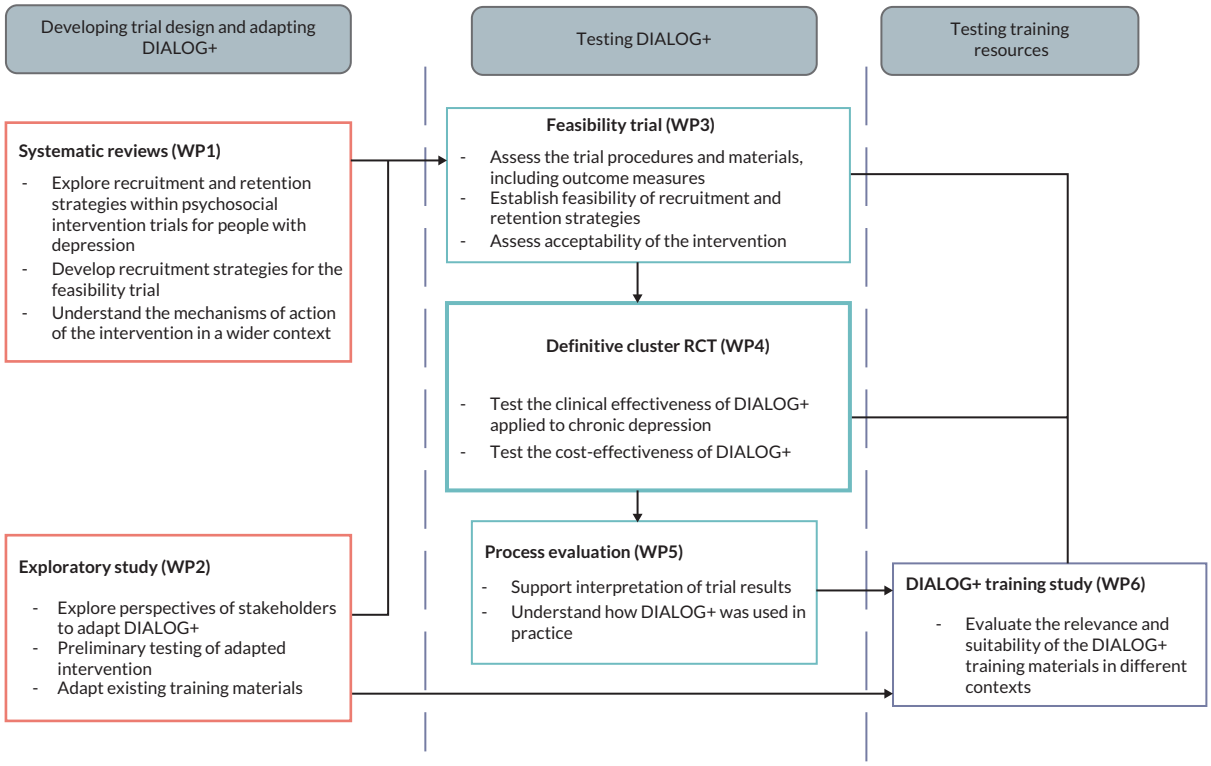

FIGURE 1 The TACK programme research pathways diagram.

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Work package 1: systematic reviews

Introduction

To help contextualise and prepare for WP4 and to better understand the issues inherent in running a psychosocial intervention trial for the treatment of depression, the first WP included a systemic review of previous depression trials. This was to help develop implementable and evidenced strategies to increase recruitment and retention and inform the trial protocol. Three further systematic reviews were conducted to: (1) contextualise intervention delivery, (2) provide initial evidence of the potential mechanisms of action and (3) allow comparison with the wider QoL literature.

Review 1: recruitment and retention strategies in depression trials: overview

The aim of the review was to: (1) identify factors which facilitate or impede recruitment and retention of participants into trials investigating psychosocial interventions for depression; (2) identify previous strategies that have successfully improved recruitment and retention and (3) develop new strategies for future WPs.

Methods

A systematic review and narrative synthesis of randomised controlled trials (RCTs) and related process evaluations, referenced in the draft National Institute for Health and Care Excellence (NICE),[1] was conducted. Eligible studies included: (1) participants diagnosed with depression (including comorbid cases) or meeting trial criteria for depression; (2) RCTs assessing psychosocial interventions (including comparisons with pharmacological treatments) or related qualitative studies; (3) interventions delivered by health professionals or trained non-clinicians (e.g. students); (4) one-to-one intervention format and (5) face-to-face delivery in at least one arm.

Screening involved two reviewers independently assessing 50% of titles, with 10% randomly cross-checked to determine inter-rater reliability (96%). Discrepancies were resolved with the chief investigator.

A standardised data extraction form captured key study details: (1) general study characteristics (title, authors, design, duration, country); (2) sample details (participant numbers, demographics, screening tools); (3) recruitment data (methods, duration, recruiters, incentives); (4) treatment information (definition, duration, provider, setting, supervision); (5) outcomes (measures, assessment time points); (6) attrition rates and data completeness; and (7) follow-up details (reminders, monitoring, qualitative components). Relevant recruitment and retention quotes were also extracted.

Results

The results of the search are presented in the flow diagram shown in *Appendix 1*, *Figure 2*. Briefly, a total of 90 manuscripts (1996–2016) were identified, with participant ages ranging from 18 to 83 years. Sample sizes varied from 10 to 621, spanning 17 countries. Most studies used parallel RCT designs, often comparing psychosocial interventions with medication or alternative treatments, with the duration of treatment ranging from 1 week to 3 years. Despite Consolidated Standards of Reporting Trials (CONSORT) guidelines (1996), reporting on recruitment and retention remained inconsistent, with information about key recruitment strategies often omitted. Study quality ratings were generally low, but reported recruitment and retention strategies are summarised below.

Recruitment incentives

Thirteen studies exceeded recruitment targets, while an equal number struggled. Three of the studies which over-recruited compared to the number of planned participants did offer incentives. This compares to only one under-recruiting study. However, incentives were rare, with only 9% of studies offering them (n = 8), thus limiting conclusions on their effectiveness.

Delivery of intervention

Face-to-face interventions showed higher attrition than remote methods (e.g. phone and online); however, only two trials directly compared the methods. Trials that allowed participants to choose their treatment arm (prior to randomisation) had lower attrition, however, whether this was directly influenced by offering a preference was unclear. It was also shown that where individuals self-referred, attrition was lower with an average of 12.5% compared to 21.6% in studies with clinician or service-level referrals.

Control group

Retention appeared influenced by the control group type. Two studies using waiting list controls had no attrition, while a third saw high attrition – though lower in the treatment arm compared to other studies.

Screening

Screening methods did not impact recruitment. Half of the studies (n = 45) used clinician referrals, with attrition ranging from 0% to 57.9%. Self-referral studies (n = 5) had lower attrition (0–21.7%), with one outlier at 33%. Studies using both methods showed a comparable attrition range (0–64%).

Systematic review discussion

Despite efforts to identify recruitment and retention strategies, limited reporting hindered conclusions. Possible reasons include journal space constraints or a lack of process evaluations. The review highlighted two key strategies: **(1) incentives** (financial compensation and expense reimbursement) and **(2) multiple assessment modalities** (phone, online, face-to-face). Additional RCT strategies included participant information leaflets, clinician training and site visits.

Additional systematic reviews

During the preparatory work, the Programme Management Group and the Lived Experience Advisory Panel (LEAP) highlighted an evidence gap pertaining to the potential mechanisms of action of the intervention (DIALOG+). Better understanding of the potential mechanisms of action was deemed important for the programme logic model and adaptation of the intervention, as well as potentially strengthening the planned process evaluation (see *Work package 5: process evaluation*). Therefore, three additional systematic reviews were completed.

Systematic review of social networks of patients with chronic depression

This systematic review[2] explored the social networks of patients with chronic depression reported in 19 articles to understand how DIALOG+ could make use of existing social networks to improve QoL. The review highlighted how individuals with chronic depression had smaller social networks compared to individuals without depression. Furthermore, individuals with long-term conditions were less satisfied with their social contacts, although it was unclear whether this was a cause or consequence of the depression. Overall, the evidence base was weak with a range of limitations.

Conceptual review of solution-focused therapy

This conceptual review[3] aimed to synthesise how solution focused approaches in adult mental health literature have been conceptualised and understood in the 50 years since its original conception. Fifty-six papers were included in the review and a narrative synthesis was conducted. A conceptual framework was produced outlining five main themes.

An individual patient data meta-analysis of quality of life for people with depression

We conducted an individual patient data of depression studies utilising the Manchester short assessment of quality of life (MANSA) to assess QoL.[4] The analysis included 1710 people with major depression and indicated variation across the 12 different MANSA domains. Satisfaction with finances, employment and mental health were rated the lowest, while individuals were satisfied with their close relationships, and relationships with family.

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Work package 2: exploratory study

Introduction

In line with the Medical Research Council framework for complex intervention development,[5] the TACK programme assessed the applicability of DIALOG+ for service users with chronic depression before the cluster randomised controlled trial (cRCT). The goal was to determine if modifications were needed to enhance the clinical relevance and acceptability of the intervention. This WP explored its suitability for both a new patient population and for use across varied settings, including primary care. The initial DIALOG+ trial was delivered in Community Mental Health Teams (CMHTs) by care co-ordinators, typically psychiatric nurses or social workers.[6–10] To broaden implementation, the study examined necessary adaptations for use beyond community care and across different professional groups.

There were three specific objectives of this WP:

1. to explore the perspective of different stakeholders to adapt the DIALOG+ intervention
2. to test the adapted intervention with 5 clinicians and 15 patients
3. to adapt existing online training materials for clinicians.

Methods

Full details are reported in our publication.[11] In brief, a non-randomised pilot study was conducted with 16 mental health professionals and 29 service users with chronic depression from 3 NHS Trusts in England (East London, Oxford Health, and Gloucester Health and Care). Clinician–service user pairs trialled the original DIALOG+ intervention during routine community care over 3 months. Individual interviews with 15 clinicians and 19 service users were thematically analysed.

Findings

Both clinicians and service users viewed DIALOG+ positively and anticipated benefits in routine care. However, barriers related to training, supervision and technology were identified. Thematic analysis revealed five key domains: **DIALOG+ structure, therapeutic communication, reflecting and monitoring, empowerment and powerlessness, and the impact of technology.** Findings indicated that DIALOG+ was suitable for chronic depression with modifications to training materials. As a result, staff training was revised to include codeveloped vignettes specific to chronic depression (in collaboration with LEAP) and troubleshooting guides for technology-related issues.

Work package 3: feasibility trial

Introduction

The final part of stage 1 was a small-scale randomised feasibility trial to see if the trial procedures were appropriate and could be executed by the trial team. The trial was registered as ISRCTN16864442 (https://doi.org/10.1186/ISRCTN16864442). The manuscript has been published by Jerome *et al*.[12] A description of the methods and main trial results, including the implications for WP4 (definitive RCT), are outlined below.

Aims

The key objectives were to assess:

1. feasibility of recruitment and retention strategies for the definitive cRCT
2. feasibility of eligibility criteria for the definitive cRCT
3. feasibility of outcome evaluation and variability of outcome measurement
4. acceptability of recording methods for evaluating treatment fidelity
5. acceptability of the adapted intervention.

Methods

Study design

A mixed-methods feasibility study was conducted involving a two-arm cRCT, and a qualitative evaluation was conducted in CMHTs in South-East England. Individuals with a clinical diagnosis of chronic depression (≥ 2 years), and their clinicians, were cluster-randomised in a 2 : 1 ratio to either the intervention (DIALOG+) or an active control [(treatment as usual (TAU) + completion of the DIALOG scale]. Participants were assessed at baseline and 6 months post randomisation by blinded assessors. For the qualitative evaluation, participants in the DIALOG+ arm were interviewed about their experiences.

Eligibility criteria

Table 1 details the eligibility criteria.

Randomisation

One aim of the feasibility study was to test the randomisation procedures. The unit of randomisation was the clinician, with clinicians and their associated patients forming clusters. Once all patients in a cluster were recruited, the whole cluster was randomised in a 2 : 1 basis to either the intervention arm (DIALOG+) or the active control arm (TAU with the additional of the DIALOG scale).

Sample size and recruitment

No formal sample size calculation was conducted. Instead, individuals were randomised 2 : 1, with the aim of achieving 30 participants in the intervention arm. Participants were recruited from three NHS England mental health Trusts: East London NHS Foundation Trust (ELFT); Barnet, Enfield and Haringey Mental Health NHS Trust (BEH); and Essex Partnership University NHS Foundation Trust (EPUT).

Trial outcomes

One of the aims of the feasibility trial was to test potential outcomes measures in preparation for the definitive trial and to determine the primary outcome. In addition to assessing potential effect sizes and variation in outcome between the intervention and control, the feasibility trial also assessed the completion rates of each measure. The outcomes included are outlined in *Table 2*.

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TABLE 1 Participant eligibility criteria

Inclusion criteria	Exclusion criteria
Service users	
18–80 years old	Primary diagnosis of current substance misuse
Clinical diagnosis of depression with a duration of illness of < 2 years	Being an inpatient on a psychiatric ward at the time of recruitment
Regular contact with a clinician from NHS mental health services	Diagnosis of an organic brain disorder, or receiving treatment for an organic, rather than a functional, disorder
Capacity to provide informed consent	
Ability to speak and understand English	
Low subjective QoL (indicated by a score of < 5 on the MANSA questionnaire)	
Evidence of current depression symptoms (as indicated by a score of ≥ 10 on the MADRS questionnaire)	
Clinicians	
Qualification as a mental health or healthcare professional	No regular contact with service users with depression
Experience of working in health care for at least 6 months	
Experience of treating individuals with chronic depression (within the last 6 months)	
No plans to leave the post within the next 6 months	

MADRS, Montgomery–Åsberg Depression Rating Scale.

TABLE 2 Feasibility schedule of measurements

	Study period			
	Enrolment	Allocation	Post allocation	
Time point	*–t1*	0	$t_{1\ (baseline)}$	$t_{2\ (6\ months)}$
Enrolment				
Eligibility screen	X			
Informed consent	X			
MANSA	X			X
MADRS	X			X
Allocation		X		
Interventions				
DIALOG+			⟷	
TAU + DIALOG Scale			⟷	
Assessments				
BDI-II			X	X
HoNOS			X	X
GAF			X	X
ICECAP-A			X	X

TABLE 2 Feasibility schedule of measurements (*continued*)

	Study period			
	Enrolment	Allocation	Post allocation	
Time point	*–t1*	0	$t_{1\ (baseline)}$	$t_{2\ (6\ months)}$
EQ-5D-3L			X	X
CSQ-8			X	X
CSRI			X	X
DIALOG+ experience questionnaire				X (intervention only)

BDI-II, Beck Depression Inventory; CSQ-8, Client Satisfaction Questionnaire-8; CSRI, Client Service Receipt Inventory; EQ-5D-3L, EuroQol-5 Dimensions, three-level version; GAF, Global Assessment of Functioning; HoNOS, Health of the Nation Outcome Scales; ICECAP-A, ICEpop CAPability measure for Adults; MADRS, Montgomery–Åsberg Depression Rating Scale.

Qualitative

Interviews were conducted with all 8 clinicians in the intervention arm and a purposive sample of 10 service users to explore the experience of using the DIALOG+ intervention. Topic guides, codeveloped with the TACK Programme LEAP, covered perceived benefits, drawbacks and suggested improvements. Clinicians also provided feedback on integration into practice, workflow compatibility and training. Participants answered a closed question on continued use to assess acceptability. Interviews were held in participants' preferred locations, with the final three conducted by phone due to COVID-19 restrictions. Audio recordings were transcribed and analysed using thematic analysis (NVivo v12) (QSR International, Warrington, UK), identifying key themes, barriers and recommendations to enhance implementation.

Procedure

Recruitment took place in six community mental health services across three NHS Trusts (ELFT, BEH and EPUT). Eligibility was determined via baseline assessments, including QoL (MANSA) and depressive symptoms [Montgomery–Åsberg Depression Rating Scale (MADRS)]. Intervention group participants attended monthly DIALOG+ sessions, using a structured, tablet-based tool to discuss life domains, set priorities and coproduce action plans. To complement quantitative findings, qualitative interviews were conducted at 6 months with seven service users and six clinicians to explore their experiences.

Results

Key findings of the cRCT related to the feasibility and acceptability of the intervention and trial procedures. In summary:

- Recruitment achieved 75% of the target sample for service users and 92% for clinicians, although organisational challenges were encountered. Retention at 6 months was 77.8%.
- Modifications to eligibility criteria improved inclusivity, addressing challenges in diagnosing chronic depression in clinical practice due to inconsistent record-keeping.
- The intervention showed potential for improving subjective quality of life (SQoL) and reducing depressive symptoms, with trends in both primary (SQoL) and secondary outcomes (depression severity). No formal significance tests were conducted, but improvements were noted in observer-rated (MADRS) and self-reported [Beck Depression Inventory (BDI-II)] measures, along with better anxiety/depression outcomes on EuroQol-5 Dimensions, three-level version.
- The DIALOG+ experience was largely positive, with 86% satisfaction and indications of improved therapeutic relationships. Challenges included balancing structured interactions with organic conversations, particularly where there was an existing relationship.
- Feasibility issues led to modifications for the future definitive trial, such as streamlined clinician-rated outcomes (replacing multi-item tools like Health of the Nation Outcome Scales and Global Assessment of Functioning with a simpler CGI scale) and improved safeguarding protocols for disclosing suicidal ideation.

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Thematic analysis of interviews revealed five key themes:

1. **Clarity and focus:** participants valued the structure provided by DIALOG+, which prompted reflection on diverse aspects of life beyond mental health. Service users reported that rating satisfaction on the DIALOG scale helped prioritise issues and set clear, manageable goals. Some clinicians noted an improved understanding of service users' holistic needs, aiding targeted interventions. However, a few participants found the structured nature redundant or restrictive.
2. **Changing conversations:** DIALOG+ fostered more in-depth discussions by introducing topics that might not have been addressed otherwise. While some participants appreciated these richer conversations, others felt constrained by the manualised approach, which occasionally hindered spontaneity.
3. **Mapping the journey:** tracking changes in satisfaction scores over time helped service users recognise progress or identify areas needing further attention. This reflective process boosted confidence and provided a sense of direction. Conversely, some found this focus on scores oversimplified their complex experiences.
4. **Changing the balance of power:** service users felt empowered to take an active role in their care, while clinicians adjusted to a more collaborative dynamic. Some participants appreciated this shift, although a few service users felt overwhelmed by the increased responsibility.
5. **Technology as an aid and hindrance:** the tablet-based interface provided a shared reference point, enhancing transparency and continuity. However, some participants found it detracted from natural interactions, reducing rapport due to reduced face-to-face engagement. Occasional technical difficulties further frustrated users.

This evaluation demonstrated that DIALOG+ is broadly acceptable and has the potential to improve outcomes by fostering structured, solution-focused interactions, although adjustments to the delivery process may enhance its usability and effectiveness. Qualitative feedback highlighted DIALOG+ as valuable for clarifying treatment goals, enhancing communication and promoting active participation. However, some found the structured approach limiting and hindered spontaneous conversations. Clinicians noted improved therapeutic dynamics but raised concerns about the tablet's impact on natural interactions.

Work package 4: definitive cluster randomised controlled trials

Introduction

The second phase involved a definitive TACK cRCT to assess whether regular use of DIALOG+ over 12 months in various clinical settings improves QoL for patients with chronic depression compared to an active control.

Secondary objectives included:

- evaluating improvements in clinical and social outcomes (e.g. depression severity, treatment satisfaction and health-related QoL)
- assessing intervention costs and cost-effectiveness.

The trial protocol is published,[13] and registered (ISRCTN11301686, https://doi.org/10.1186/ISRCTN11301686), detailing methods, outcomes and eligibility. The main paper is under review, with a summary of methods and key results provided below.

Trial methods

Trial design

The trial was a two-arm, cRCT conducted across nine NHS sites in England, covering urban and rural locations. Allocation was concealed from assessors, statisticians, health economists and the principal investigators. The trial ran from June 2019 to February 2023, including a 7-month suspension from March 2020 due to COVID-19 restrictions.

Clinicians allocated to the intervention arm used DIALOG+ during routine sessions for 12 months, while the control arm followed routine care but completed the 11-item DIALOG scale on a tablet without clinical input. This was to control for frequent QoL scale completion and use of an iPad during routine clinical appointments. Sessions were delivered within routine care settings.

Clinicians aimed to provide monthly sessions for 6 months, with additional sessions at months 8 and 10 as needed. Data were collected at baseline, 3, 6, and 12 months, as shown in the CONSORT flow diagram in *Appendix 2*, *Figure 3*.

Randomisation

The same eligibility criteria as within the feasibility study were utilised. Clinician–patient clusters were randomly allocated (1 : 1) to either DIALOG+ or the active control. Clustering by clinician minimised potential contamination effects. An independent statistician conducted remote randomisation, and clinicians were trained before initiating the intervention. Clinicians could not begin delivery of either the intervention or active control until training was received and they had received an iPad. The first randomisation occurred on 9 September 2019, and the last on 8 March 2022.

Sample size

The initial sample size calculation was based on data from the original DIALOG+ trial, with 448 service users needed to give an analysable sample of 358 (179 per group).

However, following analysis of the feasibility trial, the power calculation was revised, integrating the correlation coefficient between baseline and follow-up, on the primary outcome (MANSA). The lower end of the 95% confidence interval (CI) for the correlation coefficient was used (0.4). All other assumptions remained the same, that is an effect

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size of 0.35 [standard deviation (SD) = 1)], power set at 90% and a design effect of 1.04. The effect size utilised that observed within the original European Prediction of Psychosis Study (EPOS) trial, and the design effect utilised a conservative estimate of the intracluster correlation coefficient (ICC) observed within the trial. The updated power calculation gave a target sample size of 376, with an analysable sample of 300 (150 per group) when a 20% dropout rate was accounted for.

Trial outcomes

The primary outcome was subjective QoL as measured by the MANSA at 12 months. The MANSA score was collected at all time points (baseline, 3, 6 and 12 months) and was derived as the mean per item of the 12-item MANSA questionnaire.

Secondary outcomes were the MANSA scores at 6-month post randomisation as well as MADRS (an observer-rated depression severity scale calculated as a total of scores on a 10-item scale), the BDI-II (a self-report depression inventory, with a total score calculated from 21 items), the CGI (a single score based on a clinician's evaluation of participant's symptom severity, rated as an integer on a scale between 1 and 7) and the Client Satisfaction Questionnaire-8 (CSQ-8) (a measure of client satisfaction calculated as the total of scores on an 8-item questionnaire), at both 12 and 6 months post randomisation.

Missing data

Pro-rating was used for the primary and secondary outcomes as indicated by the authors of each assessment measure. Where no guidance was provided, a '20%' rule was applied such that if an individual had > 0% and ≤ 20% of missing items for a given scale, the score was calculated based on imputing the mean of the recorded items. If > 20% of items were unrecorded, the summary score for that outcome was treated as missing.

The full statistical analysis plan can be found in *Appendix 3*, below a summary is provided.

Statistical analysis: primary outcome

Data on trial patient participants were linked to treatment allocation through a unique clinician ID. This was then mapped to a master list of randomisations comprising data on clinician ID, treatment group and the date of randomisation. Baseline data on all randomised participants are presented for the following characteristics: age, gender, marital status, ethnicity, first language (English or other), educational attainment, employment status, receiving/not receiving state benefit, accommodation status, primary diagnosis (*International Classification of Diseases* codes).

Unless otherwise stated, analyses were carried out on an intention-to-treat basis, so all participants included in the analysis were considered to belong to the treatment group to which they were randomised. All eligible, randomised patients with a recorded outcome were automatically included in the analysis in addition to those for whom the outcome was missing but could be imputed from other available data.

The primary outcome (MANSA-score at 12 months) was analysed using a mixed-effects linear regression model with Gaussian error. In addition to treatment arm (fixed effect; intervention arm vs. control arm), the following covariates were included for statistical adjustment: baseline MANSA score, clinical site (both as fixed effects) and clinician (random effect as an intercept). To supplement the main MANSA analysis, data are presented on response rate to questions 4, 5, 9 and 10 from the MANSA schedule (yes/no answers) at 12 months in addition to estimated treatment difference expressed as an odds ratio, associated 95% CI and *p*-value (analysis; mixed-effects logistic regression using the same model specification as for the primary analysis).

All secondary outcomes were analysed following the same specification, albeit with the baseline measure score as a covariate chosen to reflect the outcome in question (e.g. baseline MADRS for analysis of MADRS at 12 months).

Secondary analysis

To assess the robustness of the primary analysis to the possible influence of 'nuisance' factors, the MANSA analysis was repeated, including the following covariates: age, gender, marital status, ethnicity, educational attainment, employment status, diagnosis category and NHS Trust and baseline outcome score. Imputation of covariates was used to substantiate analysis if > 5% of participants with a valid outcome were discarded from the initial complete-case analysis due to missing covariate data.

Sensitivity analysis

Sensitivity analyses were conducted for: (1) the primary outcome of MANSA at 12 months and (2) the MADRS and BDI-II at 12 months, to assess the impact of missing data under reasonable assumptions about the behaviour of those lost to follow-up. Missing outcomes were imputed based on selected characteristics (age, gender, ethnicity, language, education level, marital status, type of accommodation, diagnostic codes and employment status), including the same outcome at earlier time points, with a random component based on model error using the 'mi impute' command in Stata® (StataCorp LP, College Station, TX, USA) (StataCorp., *Stata Statistical Software: Release 17*, 2021). The primary analysis was rerun on the resulting data set, and this was repeated over a number of similarly imputed data sets (N = 50), with results averaged according to a multiple imputation approach. Results and estimates from the sensitivity analysis were compared against those from the primary analysis to ascertain the impact (if any) of loss to follow-up.

Mediation analysis

Mediation analysis was carried out to assess whether the treatment effect on QoL at 12 months (MANSA) is mediated through a reduction in depression scores at 6 months, using structural equation modelling (SEM). This involved developing a model that specifies the relationship in terms of a pathway between the treatment, depression and QoL variables and then testing whether the model fits the observed data. Two separate models were run, one where depression was defined on the MADRS scale and the other on BDI-II scale.

Per-protocol analysis

To evaluate treatment fidelity, a per-protocol analysis was conducted, including only participants who received > 3 DIALOG+ or control sessions.

Longitudinal analysis

To address potential bias due to attrition and subsequent missing data, a linear mixed-effects model was conducted with MANSA scores at all time points as the dependent variable. The model included a random effect for site and, within site clusters, cross-classified random effects of time and patient.

Mode-of-delivery analysis

The main analysis was revisited with an effect for mode of delivery of treatment [face-to-face, remote (online or over the phone) or mixed] included in addition to the interaction between mode of delivery and treatment. If the interaction term proved to be non-significant, the default approach was to fit and report the model, including main effects only. This analysis was motivated by an anticipated change in intervention delivery following the COVID-19 pandemic.

Statistical results

Participant flow

A total of 366 service-user participants were randomised to the trial, representing a 97.3% recruitment rate (190 participants were allocated to the intervention group, and 176 were allocated to the active control group). Four hundred and forty-four patient participants were consented and screened, of whom 33 failed screening (the majority due to not having an adequately low QoL). One intervention arm participant died before intervention delivery began. Therefore, a decision was made to exclude that individual's baseline data from statistical analysis. The baseline characteristics of participants are detailed in *Appendix 4*, *Tables 10*–*12*.

Two hundred and fifty-eight clinicians were identified and screened across the nine trial sites. Of these, 226 signed a consent form, but only 128 were randomised. The main reason clinicians were not randomised was due to an inability

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identify enough eligible service users from their caseload. Therefore, 128 clusters were randomised, with an average cluster size of 2.9 (range 1–6). The average cluster size in each trial arm varied marginally, with an average intervention group cluster size of 3.0 (mode 2) and an average control group cluster size of 2.7 (mode 3). As the average cluster sizes were very small, the ICCs were not presented due to issues with the potential reliability of estimates.

A full CONSORT diagram is shown in *Appendix 2*.

Clinician training

Of the 128 randomised clinicians, 119 received training. Clinicians allocated to the intervention arm received a standardised training presentation on the developmental history of the intervention, how to apply the DIALOG scale and how to navigate the intervention mobile application. Clinicians allocated to the active control arm received a much shorter training session, outlining how to download the DIALOG app and how to access and use the DIALOG scale.

The DIALOG+ training sessions lasted, on average, 67.61 minutes (range 19–141 minutes). Comparably, active control training sessions lasted, on average, 21.66 minutes (range 4–71 minutes).

Training occurred, on average, 27 days after the date of cluster randomisation, apart from three clinicians who were randomised in February and March 2020 and had their training delayed by several months due to COVID-19 restrictions.

Nine clinicians withdrew from the trial before they received training (two due to leaving the Trust, one due to sickness, two due to being randomised before COVID restrictions and being unwilling to participate when the study restarted, and four due to unspecified reasons).

Six intervention clinicians requested top-up training, which involved a more reflective, one-to-one, hour-long session between the clinician and the trial manager during the intervention delivery period.

Primary and secondary outcomes

The primary outcome was assessed in 290/366 patients at 3 months (79%; 190 experimental, 176 control), 280/366 at 6 months (76.5%; 149 experimental, 131 control) and 269/366 at 12 months (73.4%; 141 experimental, 128 control). This represents a 73% follow-up rate at the primary outcome time point.

The implementation of the DIALOG+ intervention and the active control intervention was variable across the trial. Like the original DIALOG+ trial,[7] just under a third of participants allocated to the intervention received < 3 DIALOG+ sessions (which was determined as the minimum dose). This was also reflected in the active control group were *n* = 58 (33%) did not complete a DIALOG scale during the trial period.

Baseline characteristics were broadly similar between the two treatment groups in relation to key characteristics, including gender, marital status, ethnicity, education and employment. A full breakdown of baseline characteristics can be found in *Appendix 4*, *Tables 10–12*.

The treatment effect and associated statistics for the primary and secondary outcomes are presented in *Table 3*.

The difference between groups on the primary outcome (MANSA score at 12 months) was of significant at the 0.05 level, with the direction of effect [0.18 (−0.00 to 0.35)] indicating an average improvement in MANSA-assessed QoL of one point on approximately 2 of the 12 composite questions. No statistically significant effects were observed for MANSA at 3 and 6 months, nor any of the other secondary outcomes at any time point.

The MANSA scale also included four binary questions (answered yes/no) which assessed further elements of QoL. At 12 months, a significant difference (p = 0.04) was observed for Q4 ('*Do you have someone you would call a close friend?*'), with a higher rate observed in the DIALOG+ group [75.2% vs. 66.4%, odds ratio (CI) = 2.10 (1.04 to 4.23)]. No other significant differences were observed.

TABLE 3 Adjusted mean difference (DIALOG+ vs. active control group) for the primary outcome (MANSA) and secondary outcomes (MADRS, BDI-II, CGI and CSQ-8) at key time points based on mixed-effects linear regression

Outcome	Time point	Intervention no. (%)	Control no. (%)	Intervention; mean (SD)	Control; mean (SD)	Adjusted mean difference 95% CI	*p*-value
MANSA	Baseline	189 (100)	176 (100)	3.52 (0.71)	3.56 (0.80)	–	–
	3 months	147 (85.96)	143 (76.47)	4.06 (0.89)	3.96 (0.99)	0.09 (−0.08 to 0.25)	0.31
	6 months	149 (91.98)	131 (71.98)	4.06 (0.93)	4.1 (0.81)	−0.01 (−0.16 to 0.17)	0.92
	12 months	141 (88.68)	128 (72.32)	4.24 (0.90)	4.11 (1.02)	0.18 (−0.00 to 0.35)	**0.05**
MADRS	Baseline	189 (100)	176 (100)	25.42 (7.01)	24.15 (7.10)	–	–
	6 months	145 (89.51)	129 (70.88)	21.91 (9.12)	19.67 (8.75)	1.32 (−0.51 to 3.14)	0.16
	12 months	135 (84.91)	121 (68.36)	20.24 (9.97)	19.78 (10.13)	−0.20 (−2.40 to 1.99)	0.86
BDI-II	Baseline	189 (100)	176 (100)	38.30 (13.17)	37.67 (12.31)	–	–
	3 months	146 (85.38)	141 (75.40)	33.8 (14.09)	33.65 (13.73)	−0.19 (−2.32 to 1.94)	0.86
	6 months	146 (90.12)	128 (70.33)	32.47 (15.34)	31.3 (13.71)	−0.90 (−3.48 to 1.69)	0.53
	12 months	131 (82.39)	120 (67.80)	30.43 (15.18)	30.42 (14.82)	−1.84 (−4.70 to 1.03)	0.21
CGI	Baseline	189 (100)	176 (100)	4.17 (0.87)	4.29 (0.96)	–	–
	6 months	101 (62.35)	89 (48.90)	3.53 (1.1)	3.63 (1.14)	−0.19 (−0.54 to 0.15)	0.27
	12 months	97 (61.01)	72 (40.68)	3.04 (1.15)	3.26 (1.26)	−0.14 (−0.53 to 0.26)	0.50
CSQ-8	Baseline	189 (100)	176 (100)	24.01 (5.07)	24.62 (4.94)	–	–
	6 months	142 (87.65)	122 (67.03)	24.44 (5.45)	25.1 (4.54)	−0.23 (−1.21 to 0.75)	0.64
	12 months	125 (78.62)	110 (62.15)	24.85 (5.32)	24.35 (5.69)	0.53 (−0.60 to 1.66)	0.36

Sensitivity analysis

Sensitivity analysis on an imputed MANSA outcome at 12 months gave an estimated mean difference of 0.16 [95% CI (−0.02 to 0.34)] between the active control and intervention groups. This analysis, conducted on a larger imputed data set that included approximately an extra 96 participants, corroborated the findings from the primary analysis, which reported an estimated mean difference of 0.18 [95% CI (−0.00 to 0.35), $p = 0.07$]. Importantly, the inclusion of the additional participants did not substantially alter the treatment effect or the statistical significance, suggesting that our primary results are not distorted by the missing data, or the specific subgroup of participants originally analysed.

Multiple regression

The primary analysis was rerun, including the additional explanatory covariates of baseline MANSA score, site (both as fixed effects) and clinician (random effect as an intercept). Inclusion of the covariates resulted in a loss of 15 (6%) of observations from complete-case analysis. As this number comprised > 5% of participants with a valid outcome, the analysis was repeated using multiple imputation. The mean difference between groups was estimated at 0.18, with a 95% CI (−0.00 to 0.35) for the primary outcome. The magnitude and significance of the estimated difference remained consistent in both analyses. Importantly, the inclusion of additional explanatory covariates did not markedly alter the treatment effect as observed in the primary analysis.

Missing data

The demographic and characteristic profiles of participants excluded from the primary analysis closely mirror those of the overall study population. Given these overarching similarities, the exclusion of this subset due to missing data does not appear to compromise the study's findings or its generalisability.

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TABLE 4 Medication effects (MADRS)

Direct effects	Adjusted mean difference 95% CI	*p*-value
DIALOG+	0.17 (−0.01 to 0.35)	0.07
Baseline MANSA	0.65 (0.52 to 0.78)	0.00
Mediation effects		
MADRS at 6 months	−0.03 (−0.04 to −0.02)	0.00
Other effects on MADRS at 6 months		
DIALOG+	2.50 (0.21 to 4.80)	0.03

Mediation analysis

Table 4 represents the mediation analyses. The direct effect of 'DIALOG+' on MANSA at 12 months showed a potential but non-significant trend [adjusted mean difference = 0.17, 95% CI (−0.01 to 0.35), $p = 0.07$]. However, significant mediation effects were observed at the 6-month interval, where MADRS scores negatively mediated the relationship [effect = −0.03, 95% CI (−0.04 to −0.02), $p < 0.001$]. This implies that 'DIALOG+' had an indirect impact on MANSA at 12 months through its influence on MADRS scores at 6 months. Baseline MANSA scores exhibited robust predictive power for 12-month outcomes [effect = 0.65, 95% CI (0.52 to 0.78), $p < 0.001$].

Similarly, as presented in *Table 5*, DIALOG+ did not demonstrate a statistically significant direct effect on MANSA at 12 months [adjusted mean difference = 0.11, 95% CI (−0.06 to 0.29), $p = 0.20$]. BDI-II scores at 6 months significantly negatively mediated the relationship [effect = −0.02, 95% CI (−0.02 to −0.01, $p < 0.001$], indicating that higher BDI-II scores at 6 months were associated with lower MANSA scores at 12 months. These findings underscore the intricate statistical relationships among DIALOG+, mediators and baseline variables in shaping the observed outcomes.

Treatment effect

A repeat of the primary analysis on participants who received three or more sessions of DIALOG+ (the minimum dose of intervention per protocol) did not result in a stronger treatment effect.

Longitudinal analysis

Table 6 includes the results of the longitudinal analysis assessing the impact of DIALOG+ on key outcomes (MANSA, BDI-II and MADRS).

The longitudinal analysis for MANSA scores showed statistically significant differences in favour of the intervention group at all three time points (3, 6 and 12 months) compared to the active control group. The *p*-values for interaction

TABLE 5 Medication effects (BDI-II)

Direct effects	Adjusted mean difference 95% CI	*p*-value
DIALOG+	0.11 (−0.06 to 0.29)	0.20
Baseline MANSA	0.61 (0.48 to 0.74)	0.00
Mediation effects		
BDI-II at 6 months	−0.02 (−0.02 to -0.01)	0.00
Other effects on BDI-II at 6 months		
DIALOG+	1.10 (−2.68 to 4.87)	0.57

TABLE 6 Results from longitudinal analysis using mixed-effects regression

	Time point (months)	Intervention; mean (SD)	Active control; mean (SD)	Adjusted mean difference 95% CI	*p*-value for interaction	Overall *p*-value
MANSA	3	4.06 (0.89)	3.96 (0.99)	0.72 (0.03 to 1.41)	0.04	0.06
	6	4.06 (0.93)	4.10 (0.81)	1.05 (0.35 to 1.75)	0.00	
	12	4.24 (0.90)	4.11 (1.02)	1.09 (0.34 to 1.84)	0.00	
BDI-II	3	33.80 (14.09)	33.65 (13.73)	−7.66 (−18.57 to 3.24)	0.17	0.00
	6	32.47 (15.34)	31.30 (13.71)	−13.92 (−25.04 to −2.79)	0.01	
	12	30.43 (15.18)	30.42 (14.82)	−16.8 (−28.8 to −4.80)	0.01	
MADRS	6	21.91 (9.12)	19.67 (8.75)	−5.61 (−12.72 to 1.51)	0.12	0.00
	12	20.24 (9.97)	19.78 (10.13)	−12.39 (−19.89 to −4.89)	0.00	

were 0.04, 0.00 and 0.00 respectively for 3, 6 and 12 months. However, the overall *p*-value for the duration of the study was not significant at the $p = 0.05$ level but was marginally higher at $p = 0.06$.

For the BDI-II scores, there were statistically significant effects in favour of the intervention group at 6 and 12 months ($p = 0.01$). When considering the entire trial duration, the effects were significant, with an overall *p*-value of 0.00.

Although the MADRS scores at the 6-month time point did not show a statistically significant difference between the groups with a *p*-value of 0.12, a significant effect in favour of the intervention group was observed at the 12-month time point and for the entire study duration (both $p = 0.00$).

Mode of delivery analysis

Due to the varying ways in which DIALOG+ and the active control were delivered during the trial (i.e. face-to-face, remotely or a hybrid model of both), on account of COVID-19 social distancing policies, a mode of delivery analysis was conducted. The interaction between mode of delivery and outcome scores was not statistically significant, as shown in *Table 7*.

Economic evaluation

A within-trial economic evaluation was conducted to assess the cost-effectiveness of the DIALOG+ intervention in comparison to the active control for patients with chronic depression in various clinical settings. We calculated costs (measured in GBP at the 2021–2 level) and health outcomes [measured by EuroQol-5 Dimensions, five-level version (EQ-5D-5L) utility] at trial participant level. The evaluation was conducted from the UK NHS and Personal Social Services (PSS) perspectives. The time horizon covered the period from randomisation to 12-month follow-up. No discount was applied. Data were analysed on an intention-to-treat basis. An incremental cost-effectiveness ratio (ICER) was calculated as the extra costs incurred to produce an extra quality-adjusted life-year (QALY). We also calculated the probability of DIALOG+ being cost-effective in comparison to the active control using willingness-to-pay (WTP)

TABLE 7 Mode of delivery analysis

	Mode of delivery	Adjusted mean difference 95% CI	*p*-value
MANSA at 12 months	Face-to-face	–	**0.56**
	Remote	0.07 (−0.33 to 0.48)	
	Mixed	0.12 (−0.29 to 0.53)	

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thresholds of £20,000 and £30,000 per QALY gained. We presented the uncertainty in point estimate of cost-effectiveness using the cost-effectiveness plane and cost-effectiveness acceptability curve (CEAC). Several sensitivity analyses were conducted.

Methods

Study measures

Outcomes

We collected outcome data at baseline, 6- and 12-month follow-up using the EQ-5D-5L,[14] MANSA[15] and ICEpop CAPability measure for Adults (ICECAP-A) instruments.[16]

The primary outcome measure for the economic evaluation was the QALY. Following NICE guidance,[17] we used responses to the EQ-5D-5L to calculate utility values by applying a mapping function.[18] The QALY was calculated using the utility values at the three time points and the area under the curve approach.[19]

Manchester Short Assessment of QoL scores and Years of Full Capability (YFC) were our secondary outcome measures. MANSA scores were calculated as the mean of the 12 individual item scores. For ICECAP-A data, we calculated the capability values by applying the UK population tariffs to responses.[20] Capability values at the three time points (baseline, 6 and 12 months) were then used to calculate YFC following the area under the curve approach.[20,21]

Costs data

A micro-costing approach was applied to collect a broad range of resource use data. We adopted the NHS and PSS perspectives and societal perspective for the participant-level cost estimation. The NHS and PSS perspectives captured the healthcare services use (inpatient, outpatient and community service), medication use and use of trial interventions (DIALOG+ or active control). Resource use from the societal perspective included three additional types, namely productivity lost, informal care provided by family and friends and contact with criminal justice services. The Client Service Receipt Inventory (CSRI) was used to collect resource use data at baseline, 6 and 12 months after randomisation, with a recall period of 6 months. Data on resource use for the trial interventions were collected using a Health Economics Inventory form designed for this trial. Additionally, clinician training time, salary bands and high-cost area supplement were collected for clinicians. Every contact between participants and clinicians for the trial interventions over the 12-month period and contact length were attempted to be recorded.

Unit cost for each resource use item was collected and then applied to the quantity of resource use for estimating total costs using the following data source for unit costs:

- Inpatient service: National Schedule of NHS costs 2020–1.[22]
- Outpatient and community service: Unit Costs of Health and Social Care 2021.[23]
- Medication: Prescription Cost Analysis statistics 2021–2.[24]
- Informal care for adults: Unit Costs of Health and Social Care 2021.[23]
- Informal care for children: Childcare Survey 2021.[25]
- Productivity lost: Annual Survey of Hours and Earnings.[26]
- Criminal Justice service: Annual Survey of Hours and Earnings[26] and HM Prison and Probation Service – Annual Report and Accounts 2020–1.[27]
- Clinician time: Pay scales for staff under the NHS Terms and Conditions of Service (Agenda for Change) for 2021–2.[28,29]

Participant-level total costs over the 12-month trial period from the NHS and PSS perspectives were estimated for the base-case analysis and complete-case analysis. In sensitivity analyses, participant-level total costs over the first 6 months of the trial from the NHS and PSS perspectives as well as participant-level total costs over the 12-month trial period from the societal perspective were estimated.

Statistical analysis

Descriptive analyses were performed for resource use, costs and outcomes by trial arm. Mean and SD were reported. We compared the difference in mean costs (and outcomes) between the two trial arms using *t*-test. Ninety-five per cent CIs were obtained using bootstrap method with 1000 replications.

Missing values were observed in costs and EQ-5D-5L utilities at baseline, 6- and 12-month follow-up. For health service resource use items, the CSRI started from a screening question to ask whether participants have used the service or not, followed by questions about the quantity and/or frequency of resource use. We handled missing values started from a simple imputation, which assumed zero resource use within a returned participant CSRI for item non-response to the screening questions and the resource use questions prior to multiple imputation (for allowing sufficient observations in the multiple imputation). Mode was applied to gender and ethnicity, which affected three observations with missing data at baseline. Multiple imputation by chained equations using predictive mean matching was then used with the assumption of missing at random (STATA command: *mi impute chained*). The imputation model included costs and EQ-5D-5L utilities at three time points and covariates that were in the analysis model (including age, gender, ethnicity, marital status, education, employment status and site). Rubin's rules were used to combine the 35 individual imputations. A randomisation seed was applied to enable reproducible imputations.

Economic evaluation

We estimated incremental costs and QALYs between the two trial arms using a bivariate generalised linear mixed-effects model, which allows simultaneous modelling of outcomes and costs over the 12-month trial period (STATA command: *gsem*).[30] The model adjusted for baseline cost (or outcome) and covariates (including age, gender, ethnicity, marital status, education, employment status and site). It also included a clinician random effect. To address uncertainty around the point estimate, we applied the bootstrap method with 1000 replications and then plotted the 1000 pairs of incremental costs and incremental outcomes estimated onto a cost-effectiveness plane. We also reported the probabilities that DIALOG+ is cost-effective using the WTP thresholds accepted by NICE at £20,000–30,000 per QALY gained.[17] Uncertainty around the point estimate of ICER and the probability of DIALOG+ being cost-effective at different WTP thresholds were further explored using the CEACs.[31]

Several sensitivity analyses were conducted to assess the robustness of the results from our base-case analysis. These are:

- performing complete-case analysis
- taking 6-months as the time horizon
- conducting analysis from the societal perspective
- using MANSA and ICECAP-A as the outcome measures.

Statistical significance was determined at the 5% level ($p < 0.05$). All analyses were performed with STATA MP17.[10]

Economic evaluation results

Resource use and costs

Participant-level resource use over the 12-month trial period is reported in *Appendix 5*, *Table 13*. On average, DIALOG+ participants spent 37 minutes per session (and attended four sessions) over the 12-month trial period, while active control participants spent 32 minutes per session (and attended six sessions on average).

Total costs and cost per item over the 12-month trial period are presented in *Appendix 5*, *Table 14*. The intervention cost was £16.86 per DIALOG+ participant and £12 per active control participant. The total costs per participant over the 12-month trial period from NHS and PSS perspectives were £3028.54 and £2729.54 for DIALOG+ and active control groups, respectively, resulting in an estimated difference of £299 (95% CI −£1734.35 to £2332.35). From the societal perspective, the total costs per participant were £15,071.60 for DIALOG+ group and £19,363.57 for the active control group, with an estimated difference of £4291.97 (95% CI −£13,196.24 to £4612.30).

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From the NHS and PSS perspectives, for both trial arms, the most expensive resource use item (base on participant level average costs) was outpatient and community services, followed by inpatient services and medication use. In both trial arms, we observed much higher participant-level total costs if the analysis was conducted from the societal perspective. This was largely driven by the use of informal care. Limited costs on criminal justice service contacts were reported in both arms.

Costs at baseline and 6-month follow-up broadly follow the similar pattern as reported in *Appendix 5*, *Tables 17* and *18*.

Outcomes

Summary statistics of the three outcome measures at baseline, 6- and 12-month follow-up, and comparisons between the two trial arms, are presented in *Appendix 5*, *Tables 15* and *16*. The average QALYs over the 12-month trial period was 0.435 for participants in the DIALOG+ group and 0.451 in the active control group, with an estimated mean difference of −0.016 (95% CI −0.090 to 0.058).

Base-case cost-effectiveness analysis and sensitivity analyses

Results from the primary economic evaluation and sensitivity analyses are reported in *Appendix 5*. In the base-case analysis, the incremental cost of DIALOG+ in comparison to active control was £114.45 (95% CI −£598.39 to £768.31). The incremental QALYs was 0.0241 (95% CI −0.0016 to 0.0478), resulting in the ICER of £4749 per QALY gained. The uncertainty around this point estimate of the ICER is shown in *Appendix 5*, *Figure 4*, with a cost-effectiveness plane. The probability of DIALOG+ being cost-effective using a WTP threshold of £20,000/QALY is 79.8%, and it is 87% at a WTP threshold of £30,000/QALY. *Appendix 5*, *Figure 5* presented the CEAC for further exploration of the probability of DIALOG+ being cost-effective under a range of WTP thresholds from £0 to £50,000.

The results from complete-case and base-case analyses broadly agreed with each other. While taking 6 months as the time horizon, DIALOG+ was unlikely to be cost-effective compared to the active control (39.5% at £20,000/QALY and 58.7% at £30,000/QALY). When we conducted the evaluation from societal perspective, DIALOG+ appeared to be a dominant intervention [with incremental cost suggested cost savings of £620.61 (95% CI −£3623.31 to £1987.38) and incremental QALY of 0.0262 (95% CI −0.0000 to 0.0504)].

DIALOG+ Experience Questionnaire results

The 'DIALOG+ Experience Questionnaire', shown in *Appendix 6*, was a purposefully developed measure coproduced with the LEAP to investigate the patient experience of receiving DIALOG+ as part of routine care. The questionnaire was completed by patient participants allocated to the intervention arm at 6- and 12-month follow-up.

Results from the experience questionnaire were very positive. Most participants were satisfied with their treatment while using DIALOG+. Sixty-one of 78 respondents said they were a little or totally satisfied (78%) after 6 months, and this increased to 85% at 12 months; 61/79 found DIALOG+ very easy or a little easy to use (77%) at the 6-month mark, and 59/79 respondents found DIALOG+ very useful or a little useful (75%) after 6 months of using it.

When asked, at 6 months, if they preferred DIALOG+ to the treatment they had received previously, 15 respondents (40%) had no preference, while 32% preferred DIALOG+ a great deal. At 12 months, 85% had either no reference or preferred DIALOG+.

Safety reporting

There were 55 serious adverse events (SAEs) reported across the lifespan of the trial. Thirty-three SAEs occurred to participants in the DIALOG+ group, 19 to participants in the active control group and 3 occurred to participants before allocation.

There were 2 deaths (1 from each arm), 1 life-threatening complication, 41 admissions to inpatient units, of which 30 were admissions into a mental health inpatient ward. The majority (*n* = 20) were associated with a suicide attempt. The other 11 admissions were to acute inpatient wards (cardiology, COVID, etc.). Forty-four individual participants experienced a SAE, with 11 of these experiencing more than one.

The Data Monitoring and Ethics Committee reviewed patient safety data every 6 months and agreed none of the SAEs were related to the trial interventions.

Discussion

The cRCT provides a rigorous assessment of the intervention's impact, incorporating both statistical and economic analyses. A small increase in SQoL in the DIALOG+ group was observed, suggesting that patients may have been better able to cope with their symptoms and their impact on daily life. Furthermore, while there were no significant decreases in symptom measures between the two trial arms, there was a borderline significant trend towards a reduction in depression severity over the 12-month study period. This was corroborated by the longitudinal analysis, which indicated an overall significant reduction in both self-reported and observed-rated depression scores.

The difference in QoL scores at the 12-month time point was marginal but still demonstrated a positive effect, equating to an average improvement of one point on approximately 2 of the 12 MANSA items. This, combined with minimal intervention costs, high patient satisfaction and preference for DIALOG+, provides a strong rationale for its wider implementation for individuals with chronic depression.

From an economic evaluation perspective, base-case analysis suggested that DIALOG+ is marginally more effective and costly over the 12-month trial period than active control. The ICER estimates indicated that, under current NICE-recommended WTP thresholds, the intervention has a high probability of being cost-effective (79.8% at £20,000/QALY and 87% at £30,000/QALY). When evaluated from an alternative perspective (i.e. societal but not NHS and PSS), the high probability of DIALOG+ being cost-effective still held (79.9% at £20,000/QALY and 83.6% at £30,000/QALY). It should be noted that a limitation within the economic evaluation was related to the large amount of missing data, with 31% of the sample missing EQ-5D-5L values and 65% missing at least one cost item (the NHS and PSS perspectives) at the 12-month follow-up. See details in *Appendix 5*, *Table 18*. Before we applied multiple imputation to handle missing values, we replaced non-response items for resource use by zero. This is a strong assumption on the resource use data.

In conclusion, WP4 indicated that DIALOG+ is a simple, low-cost intervention requiring < 70 minutes of clinician training, yet it has the potential to bring about small but significant improvements in QoL for a chronically unwell population. Given its cost-effectiveness, patient satisfaction and patient preference, DIALOG+ warrants broader implementation as a structured intervention for chronic depression.

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Work package 5: process evaluation

Introduction

Work package 5 comprised an embedded, mixed-methods process evaluation within the cRCT to understand how DIALOG+ was implemented and experienced within the trial.

There were three data collection streams within WP5:

1. Qualitative interviews with participants who received DIALOG+ and clinicians who delivered it. Interviews explored their experiences of delivery/receipt of the intervention.
2. Analysis of extracted DIALOG+ data, indicating the number and frequency of DIALOG+ sessions and TAU sessions. DIALOG scale scores were also extracted for each recorded session.
3. Assessment of adherence to the DIALOG+ manual through analysis of recordings of DIALOG+ sessions delivered as part of the trial.

The process evaluation manuscript is currently being prepared for submission and is briefly summarised below.

Post-intervention interviews

Service users and clinicians who were allocated to the intervention arm were invited to be interviewed about their experiences of using DIALOG+ after their final assessment at 12-month post randomisation. A sampling framework was developed for both service users and clinicians to ensure maximum variation in experiences. Service users were purposively sampled based on: (1) the level of engagement with the DIALOG+ intervention as indicated by the number of DIALOG+ sessions received; (2) improvement in QoL or not, as measured by MANSA score at baseline versus at 6-month follow-up and (3) level of satisfaction with DIALOG+ as measured by the DIALOG+ Experience Questionnaire. Additionally, participant characteristics such as (4) age, (5) gender and (6) study site ensured a varied sample.

Mental health professionals were purposively sampled based on the following criteria: (1) DIALOG+ implementation based on the number of completed DIALOG+ sessions; (2) professional background; (3) clinical setting; (4) gender and (5) study site. The sampling framework for both participant groups is presented in *Appendix 7*. The sampling framework for service users is shown in *Appendix 7*, *Table 19*, and the framework for clinicians in *Appendix 7*, *Table 20*. Service user and clinician interview data were analysed separately but using the same thematic analysis approach.

Post-intervention interview findings

In total, 43 service users and 25 clinicians were interviewed. Service users were sampled from 7 of the 9 trial sites (Gloucester = 14, Oxford = 8, Sheffield = 6, Essex = 6, Somerset = 6, Devon = 2 and SLAM = 1). Twenty-nine were female and 14 male, with 15 interviewees falling in the 18- to 40-year-old age range, 20 being between 41 and 65 years, and 8 were over 65 years. Thirty-seven of those interviewed (86%) had an existing relationship with their clinician, while the remaining 6 were newly referred at the start of the trial. Thirty-three received four or more sessions of DIALOG+, while six received three sessions (the minimum required for an adequate dose of the intervention as per the protocol) and six received two or less sessions.

Clinicians were sampled from six trial sites (Gloucester = 8, Oxford = 6, Essex = 4, Sheffield = 3, Somerset = 2 and SLAM = 2). Eighteen were female and 7 were male and came from a range of professional backgrounds (mental health nurse = 9, psychiatrist = 5, occupational therapist = 3, psychologist = 3, social worker = 2, support worker = 2 and other = 1). Ten of the clinicians were rated as highly experienced (defined as having 11+ years in mental health), 7 had between 3 and 10 years of experience and 3 had < 3 years of experience.

Service-user participant themes

Analysis of service user data resulted in six themes: (1) structure and focus, (2) getting a bigger picture, (3) mapping the recovery journey, (4) focusing on strengths, (5) working on solutions and (6) the impact on therapeutic relationship.

Theme 1 was about the structure and focus brought to clinical conversations as a result of the DIALOG+ framework. Although many thought more structure was a benefit, others found that it was 'too prescriptive' and was to the detriment of free-flowing conversations with their clinician.

Theme 2 centred around how working holistically allowed for new experiences within routine care sessions. Talking about different domains of QoL uncovered the connections between them and ultimately allowed for a deeper exploration of their mental health, which individuals found beneficial.

Theme 3 looked at how mapping the recovery journey (through completion of a standardised patient reported outcome measure) allowed for deeper reflection by the service users regarding their life and well-being. The process of tracking change over time was appreciated by the majority; however, some felt there was often a disconnect between their lived experience and the scores on the DIALOG scale, and many found it onerous to rate satisfaction with life repeatedly, particularly when little change was evident.

Theme 4 outlined how focusing on strengths (rather than deficits) was appreciated by service users as it highlighted the resources and strategies available to them. Working through the four-step approach and being solution-focused introduced a more hopeful approach, one focused on positive change, which could be more widely applied in their day-to-day lives.

Theme 5 expanded upon the previous theme by outlining how actively working on solutions was also beneficial to recovery. It was not just about talking about solutions but the process of actually making a plan, reviewing it and collaborating with personal networks to achieve the goal, which was seen to be helpful. There were, however, limitations to this, such as people often lacking motivation or feeling under pressure to achieve.

The final theme, Theme 6, centred around the impact of DIALOG+ on the therapeutic relationship. There was a positive impact in that it enabled more patient-centredness and improved rapport. However, some service users did feel that such a structured approach made interaction impersonal and that the technology presented barriers to improved rapport, for example, the clinician focusing their attention on the tablet during intervention delivery.

Clinician participant themes

Analysis of clinician interview data resulted in seven themes, many of which echoed the service user findings: (1) structured format for conversations, (2) getting a bigger picture, (3) monitoring change, (4) focusing on strengths, (5) working on solutions, (6) the impact on therapeutic relationship and (7) the impact of technology.

Theme 1 highlighted how clinicians saw the benefit in the additional structure and focus brought about by the DIALOG+ intervention. Such structure initiated in-depth conversations and allowed greater insight into the lives of individuals. However, additional structure also meant clinical conversations could feel restrictive and/or repetitive, with natural flow sometimes feeling hindered or follow-up questions about certain issues being prevented.

Theme 2 centred on the concept of working holistically and how completing the DIALOG scale and touching on different areas of QoL enabled clinicians to learn more about the individual and see the intraconnectedness of these areas with the mental health of the service user. Working holistically did, however, lead to some clinicians dealing with the difficulty of introducing areas that they felt they could not adequately address or do anything practical about, for example housing or employment.

The integral element of repeated QoL scoring meant that change was constantly monitored by DIALOG+, and Theme 3 outlined how this was experienced by clinicians. Mapping patterns of change allowed both the clinician and service user to identify issues, track mood and evidence change over time. Although this often led to constructive conversations

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about change, some clinicians felt that quantifying feelings can often be unreliable and some encountered challenges in obtaining the scores in the first place.

Theme 4 evidenced the sense of optimism that clinicians felt working in a strengths-based way, where the focus of conversation was moved away from problems and onto resources the individual already has. This was seen to break the cycle of negative thinking and reinforce positive behaviours that lead to change, but there was a myriad of challenges in being 'strengths-based', not least when the care system was often focused on the deficit of the individual.

The solution-focused elements of DIALOG+ were something that was integral to the clinician experience, and Theme 5 comprised data that outlined both the strengths and limitations of care planning in a way that prioritised solutions.

Theme 6 showed that DIALOG+ was a new way of working for most and, by its very nature, it meant that the ratio of contributions during usual sessions was changed so that service users had to be engaged much more in the process and contribute more in both information giving and applying the philosophy to their lives. Some clinicians experienced resistance from service users, whereas others found that DIALOG+ facilitated collaboration and deepened trust.

Finally, Theme 7 focused on the varying ways that using technology impacted the experience of care delivery. There were practical issues, such as difficulties with app navigation and a lack of integration with clinical systems and relational issues, such as impacting rapport and connection. However, technology could aid collaborative working in some ways.

Post-intervention interview discussion

The table listing the themes and related subthemes for both participant groups can be found in *Appendix 8*. The themes for both service user and clinicians were fairly comparable and oriented around the same concepts, apart from the impact of technology, which was discussed a great deal more by clinicians than service users. This may be because it was the clinician's responsibility to use the tablet and app, and they were more aware of both the benefits and limitations that were afforded by its presence in the clinical space.

The service user data were analysed with the support of the TACK LEAP, and three members were trained in thematic analysis techniques to support them in contributing to the analytic process. This was beneficial not only to the project, where the insight of lived experience created a richer understanding of the interviews, but was also a benefit to the personal and professional development of the LEAP members. LEAP members are being actively engaged in the process of drafting the manuscript for publication.

Extracted tablet data analysis

All clinicians, regardless of allocation, were asked to extract their tablet data at the point where all patient participants in their cluster had completed 12-month follow-up assessments. The DIALOG app was designed to store data about app usage, including date and time of sessions, number and frequency of sessions, the DIALOG scores given per session and the action items set (for those in the intervention arm). This was extracted as a comma separated values (.csv) file by the clinician and then e-mailed to a member of the research team via NHS to NHS e-mail.

Data from the files was entered onto a SPSS (Statistical Product and Service Solutions) [SPSS Inc., Chicago, IL, USA (version 18 and below)] database to allow for preliminary analysis. A full content analysis of the action items set, and further investigation of the QoL scores across the project timeline (particularly during periods of COVID-19 lockdown), was beyond the scope of the WP, but this is planned to be completed in the future.

Extracted tablet data results

A total of 496 DIALOG+ sessions and 489 control group sessions were extracted from clinician tablets. These figures likely underestimate actual sessions due to remote consultations during the COVID-19 pandemic. Some control group sessions were recorded on paper, with participants mailing completed forms to the research team for data entry.

In the intervention group, session frequency ranged from 1 to 12 over 12 months. According to protocol, clinicians were expected to conduct monthly DIALOG+ sessions for 6 months, with optional continuation up to 12 months. The mean number of sessions recorded was 3.64 (SD = 2.27), with 49.2% of participants receiving 3–6 sessions and 12.3% receiving more than 6.

In the control group, service users completed the DIALOG scale after each routine session without clinician input, resulting in a wider range (1–22 sessions). This reflects the scale's use in all clinical encounters rather than just care planning. The mean number of sessions was 4.83 (SD = 3.71), with 46.6% of participants completing three to six sessions and 22.2% exceeding six.

Across both groups, DIALOG scores ranged from one to seven. The lowest mean score was for mental health (3.45, SD = 1.5), and the highest was for meetings with health professionals (5.83, SD = 1.09), consistent across both trial arms. *Table 8* shows the average scores for all 11 items on the DIALOG scale by group.

When service users were asked if they needed additional help in each of the QoL domains, the most frequent request for help was with mental health (62.7% of DIALOG+ sessions). The second most frequent request for help was with physical health (38.7%) and the third was medication (29.4%). Three hundred and thirty-seven (67.9%) of the individual DIALOG+ sessions had at least one action item following on from the structured four-step discussion.

Adherence ratings

Both clinician and patient participants were asked at the point of consent whether they agreed to have their treatment sessions recorded (either via audio or video means). The number of 'viable dyads' consenting was documented. During treatment, delivery a subsample of those consented were reapproached to ask if a session could be recorded. These audio–visual data were planned to be used to assess clinician adherence to the DIALOG+ manual and how well the clinicians interpreted the training received.

The DIALOG+ Adherence Checklist (available to download from www.elft.nhs.uk/sites/default/files/DIALOG%20Adherence%20scale%20final_v1.0_%2809.June_.2020%29.pdf) was used to assess clinician adherence to the DIALOG+ manual. The checklist was previously developed by a working group of academics, clinicians and researchers working on multiple projects and trials implementing DIALOG+ as a means to assess fidelity. It was originally created for

TABLE 8 Overall mean average ratings for items on the DIALOG scale by trial arm

	Intervention group		Active control group	
DIALOG scale item	Mean score (SD)	*N*	Mean score (SD)	*N*
Mental health	3.45 (1.46)	464	3.18 (1.51)	393
Physical health	3.63 (1.48)	462	3.47 (1.46)	424
Job situation	4.40 (1.72)	449	3.66 (1.73)	407
Accommodation	5.48 (1.49)	463	5.11 (1.54)	425
Leisure activities	3.77 (1.46)	465	3.38 (1.48)	425
Partner/family	4.50 (1.65)	462	4.38 (1.88)	425
Friendships	4.39 (1.55)	463	4.15 (1.69)	427
Personal safety	4.91 (1.63)	464	4.68 (1.75)	426
Medication	4.84 (1.40)	464	4.52 (1.50)	424
Practical help	5.31 (1.33)	459	4.97 (1.38)	426
Meetings	5.83 (1.09)	458	5.68 (1.19)	425

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the EPOS trial[7] but has since been amended following changes and updates to the DIALOG+ manual (the latest version is 3.0). The checklist assesses how well clinicians adhered to the intervention manual and to what extent they delivered the key components of the intervention.

There are three subscales within the checklist: (1) 'DIALOG+ procedure' has a score range of 0–7 and assesses the use of the DIALOG scale and how QoL ratings are reviewed; (2) 'four-step procedure' has a score range of 0–9 and assesses the solution-focused elements of the dialogue between clinician and service users and (3) 'quality of interaction' has a score range of 0–3 and assesses the clinical quality of the interaction, including communication style.

By the end of the trial, six audio recordings had been made by three clinicians of their DIALOG+ sessions. This low number of recordings was due to a number of factors, including: clinician difficulty with recording devices, reluctance to be recorded from both the clinician and service user perspective and limited capacity of the involved clinicians. No video recordings were made for the above reasons as well as the difficulty with equipment set up during COVID-19 when social distancing policies and equipment usage policies were in place.

The six recordings were made between August 2021 and May 2022: two of the recordings were the third DIALOG+ session, three were the fifth DIALOG+ session and one was the eighth DIALOG+ session.

All three clinicians came from Gloucestershire Health and Care NHS Foundation Trust. One clinician was a mental health nurse, one an occupational therapist and one a support worker. Experience in mental health ranged from 5 to 21 years, and all were female.

Application of the adherence checklist resulted in generally high scores across the six recorded sessions. The global adherence score ranged from 13 to 17, with a mean average score of 14.7 (although there are no specific thresholds for quality categories, a score of over 14 is considered a 'good session' of DIALOG+). In terms of the three subscales, the average score for 'DIALOG Procedure' was 4.7 (range = 3–6), for the 'four-step procedure' was 7.17 (range = 5–9) and for 'quality of interaction' was 2.83 (range = 2–3).

Clinicians often struggled with the four-step conversation framework, which applies solution-focused therapy to collaborative dialogue aimed at setting actionable goals. However, fidelity assessments indicated overall strong communication and positive regard, with five of six sessions receiving the highest quality rating (3/3).

These findings should be interpreted with caution due to the small sample size, single-site data and potential selection bias favouring confident clinicians. Future research should ensure a more representative sample and incorporate video data for comprehensive fidelity assessment.

Despite these limitations, the findings suggest improvements to DIALOG+ training, particularly in clarifying prompts within the four-step procedure. Enhanced guidance could better equip clinicians to integrate solution-focused principles, fostering more effective, collaborative and goal-oriented discussions in care planning.

Work package 6: DIALOG+ training study

Introduction

Increasingly, individuals with complex needs are being treated within primary, specialist secondary and tertiary services, as well as community care. Despite this, most trials on psychosocial interventions for this population have recruited from CMHT settings. It was, therefore, the aim of WP6 to refine the DIALOG+ training materials and trial these materials with different healthcare professionals. We then aimed to assess the feasibility of training as well as intervention use within different clinical settings where individuals with chronic forms of depression may be treated.

Method

The original intention was for all training sessions to be conducted online, but following the findings from WP2, where possible training was facilitated face-to-face by an experienced trainer. Additionally, the original research plan was to recruit and train 20 health professionals from ELFT, who work with people with depression, with the following professional backgrounds: (1) primary care nurses, (2) assistant psychologists, (3) occupational therapists and (4) inpatient staff. However, due to the interest in DIALOG+ across the country, and the wider implementation of the intervention as part of standard care planning within ELFT, this inclusion criteria was expanded to include any NHS Trust, including any health professional working with serious mental illness (SMI).

Delivery of training

Training was delivered across four NHS Trusts (Kent and Medway NHS and Social Care Partnership Trust, Essex Partnership NHS Foundation Trust, West London NHS Foundation Trust and Oxford Health NHS Found Trust) between October 2021 and April 2023, involving 13 individual training sessions. Training was delivered in a group by a researcher from the TACK study, although two clinicians did receive one-to-one training.

Training sessions were developed and standardised based on feedback from all previous WPs (particularly WP2 and WP5). They lasted between 90 and 120 minutes and involved learning about the developmental background of the approach, the existing evidence base it and video testimony from service users and carers. The session would end with approximately 30 minutes of skills practice where clinicians would practice the application of the intervention using clinical vignettes. When required, information would also be given as to how make the DIALOG+ app compatible with existing clinical systems.

A total of 109 clinicians were trained: Kent and Medway (n = 10); Essex (n = 22, across inpatient, older adult, OT, and forensic teams); West London (n = 61, forensic, MINT, AMHS teams); and Oxford Health (n = 16, third-sector supported recovery teams).

Clinician training survey

Immediately after the training session, clinicians were encouraged to complete an online, post-training, feedback survey. The survey was divided into three sections, the first collected background and occupational data such as age, number of years working in mental health and professional role. The second section presented statements about the training session, such as '*the training seminar met its stated aims and objectives*' and asked respondents to select their level of agreement on a five-point Likert scale ranging from Strongly Agree to Strongly Disagree. The third section was comprised of four open text boxes.

Survey results

In total, N = 86 people responded to the survey (Kent and Medway NHS and Social Care Partnership Trust, n = 5, West London NHS Foundation Trust, n = 61, EPUT, n = 11, Oxford Health NHS Foundation Trust, n = 7, and n = 2 did not specify which Trust they were from).

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Of 86 respondents, 34.9% were under 35 years old, 31.4% were aged 35–49 years, 30% were aged 50–65 years and 3.5% over 65 years. Average experience in mental health was 9.38 years (SD = 8.61). Roles included mental health nurses (43%), occupational therapists (19.8%), psychologists (7%), support workers (5.8%) and 20% in other roles (assistant psychologists, administrators and students).

Overall and across all professions and sites, training was well received; 90.7% of participants agreed it met its aims, 80.2% felt it met expectations and 81.4% found it covered all necessary information for DIALOG+ implementation. Confidence in using the app was reported by 69.8% (< 10% disagreed), while 66.3% felt confident in delivering DIALOG+. However, when asked about the main barriers to implementation, the most popular response was time and resource issues (47.7%), then technical equipment issues (38.4%) and then confidence with technology (33.7%).

Clinical case vignettes were helpful for 40.7%, but 37.2% found them not applicable to their context, suggesting a need for service-specific examples. Video demonstrations were well received (67.4% agreed they enhanced training). Free-text responses underwent content analysis

The free-text questions at the end of the survey were analysed with conventional content analysis.[32]

In-depth, post-training qualitative interviews

Clinicians who had delivered DIALOG+ as part of their clinical work for at least 3 months following the training were approached to participate in an in-depth interview. This was to explore how training was applied in services and investigate if identified training needs were different in hindsight after actual intervention delivery. Additionally, project managers and clinical directors who were involved with the implementation and roll-out of DIALOG+ as a care planning tool (and replacement for the Care Programme Approach) within local services were interviewed. This was to identify what the extant and predicted barriers were to successful implementation (particularly training needs).

Post-training interview analysis

Framework analysis[31] was used to analyse the transcribed interviews. The framework method is a staged approach to the management, summarisation and analysis of data, which allows for multidisciplinary working, particularly within health research. Interview data from four transcripts were initially coded independently by two analysts, who then met to develop a working analytic framework. This initial framework was then applied to all interview transcripts before a 'matrix' was produced and illustrative quotes were then charted into this matrix, separated by interviewee. This matrix was then used to inform the interpretation of the data and produce final themes.

Post-training interview findings

Interviews took place between March and July 2023. Fourteen clinicians were interviewed from three different NHS Trusts (Oxford Health NHS Foundation Trust, *n* = 6; West London NHS Foundation Trust, *n* = 4; EPUT, *n* = 4). Clinicians came from a range of service settings, with six coming from community tertiary care services, three from inpatient units, two from forensic services, two liaison psychiatrists and one from psychological services. The average length of experience in mental health was 15.5 years, with a range of 8–22 years.

Overall, there were six themes that described the experience of receiving and implementing DIALOG+ training. Themes and subthemes can be seen in *Table 9*.

Discussion

Clinicians from non-CMHT settings were content with the generic DIALOG+ training received. They found the trainers to be knowledgeable and supportive and reported benefiting from the group format structure. However, when applying the 'generic' training resources, there was a lack of specificity and/or relevance of the clinical vignettes to their context. It is important therefore to ensure that training is adapted to different clinical contexts. Although DIALOG+ was developed and is promoted, as a generic intervention, future training sessions should pay attention to the examples and

TABLE 9 Themes produced from framework analysis of clinician interviews about the experience of DIALOG+ training

Theme	Subthemes
1.0. Experience of training	• Focus, scope and clinical relevance • Length of training • Group size • Who is the training facilitator? • Inclusion of lived experience
2.0. In-training support needs and facilitating factors	• Technical support • Skills practice • Group training dynamics
3.0. Clinical reality of applying skills and knowledge	• Confidence with app (technical aspects) • Confidence with intervention (clinical elements) • Barriers to application • Compatibility with routine practice
4.0. Sustainability of training	• Need for supervision • Need for ongoing support • Need for additional resources
5.0. Benefits of training	• Benefits of attendance • Continued Professional Development
6.0. Suggestions for improvement	• Improving training content • Limitations of the app • Limitations of received training

language used to support the training. Clinical vignettes should be coproduced with current users to underpin the skills practice that are specific to the patient group and/or setting.

The length and depth of training were appraised differently by different clinicians, with some thinking that training needed to be short and to the point, while others requested extended training sessions that included the underpinning philosophy of the approach. However, ongoing supervision, whether in a group setting or one to one, was perceived as paramount to ensure the continued delivery of high-quality care.

Training study conclusion

Although the general content of the DIALOG+ training is relevant to most mental health staff, there is a requirement to amend some elements of the training to ensure proper engagement. Clinical vignettes should be context-specific, and terms and references used within the training session should be appropriate for the clinical setting. These are relatively simple adjustments to make but could have a large impact on the confidence of staff and how likely they are to use DIALOG+ in the future.

Future research should also investigate how ongoing supervision can support the implementation of DIALOG+ and which ongoing training models (frequency of supervision sessions, continued training availability, etc.) lead to the highest fidelity and highest patient satisfaction.

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Patient and public involvement

The TACK LEAP was involved in all stages of the trial planning and delivery. The LEAP members met regularly throughout the whole programme and were influential in ensuring that the trial was designed in such a way to centre the participant experience.

Notably, the LEAP members were involved in the selection of outcome measures to be used in the trial, and they developed the bespoke DIALOG+ Experience Questionnaire as part of a workshop so that aspects of service user engagement and experience with novel interventions were captured as a process measure. All participant-facing documents such as information sheets and consent forms were developed and reviewed by the panel to ensure appropriate and sensitive language, and recruitment strategies were discussed on an ongoing basis to maximise them where possible. The LEAP also provided a structure and model for patient involvement in other countries, notable within the Global South, where user-led research and participation is lower. The TACK LEAP held online meetings and training sessions with LEAPs in India, Pakistan and Latin America, offering their personal experience and research expertise to others and developing a network of lived experience which will be a resource for future projects.

Finally, during the COVID-19 pandemic, when research activities were amended to allow for remote consenting and remote data collection, the LEAP was instrumental in coproducing standard operating procedures (SOPs) to guarantee that the new processes were completed in a way that respected participants and centred any concerns or worries they may have. As part of this process, we implemented 'welfare checks' with all participants 1 week following data collection time points and developed resources to support them once their participation was complete.

The efforts to meaningfully involve the experts by experience in the development and testing of DIALOG+ were presented as part of a Symposia at the Joint Congress of the World Association of Social Psychiatry (WASP) and the Faculty of Rehabilitation and Social Psychiatry, in London, 2023. The contributors (including panel members) published the following article about their experience of user participation: https://doi.org/10.4103/wsp.wsp_13_23.

Dissemination

Dissemination activities have taken place throughout the programme, covering publication of research findings in high quality journals, symposium, oral presentations and poster presentations at international and conferences and presentations at local events [(particularly patient and public involvement (PPI) events]. Journal articles, where published, have been referenced throughout this report and are included as a list, alongside symposia and major conference presentations in the list of dissemination activities. A list of all dissemination activities has been included below.

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General discussion

Despite the restrictions due to the COVID-19 pandemic, the programme was able to proceed with only minor adjustments to the methodology used (which are outlined in detail in *Changes to the programme due to COVID-19*). Briefly, this included moving interviews, focus groups and LEAP session online during social distancing and changing mode of delivery for the intervention. As the interventions to be tested were delivered during routine care, clinicians and service users were instructed to continue in whatever capacity was mandated by their clinical service. This meant remote online and phone delivery as well as face-to-face. Minor adjustments were made to the sample size during the programme due to refined power calculations as outlined within the *Methods*.

Reflections on successful and unsuccessful elements

Successful aspects:

- **DIALOG+ feasibility and impact:** the programme successfully adapted DIALOG+ for individuals with chronic depression, a population often resistant to standard treatments. The structured and solution-focused approach provided modest yet meaningful improvements in subjective QoL (MANSA scores), which is significant, given the long-term challenges faced by this group.
- **Cost-effectiveness:** despite the additional costs of intervention delivery (£299 per participant), DIALOG+ demonstrated cost-effectiveness with an ICER of £4749 per QALY gained. This reinforces its potential as a scalable addition to routine care.
- **Positive reception:** service users appreciated the empowerment gained through structured sessions, and clinicians highlighted the intervention's utility in creating more patient-centred care plans. The intervention also fostered reflective practices among participants, helping them recognise strengths and set achievable goals.
- **Robust trial design:** the programme successfully executed a large, cRCT across multiple NHS sites, including urban and rural settings, underscoring the intervention's scalability and applicability across diverse contexts.

Unsuccessful aspects:

- **Challenges in engagement and fidelity:** a significant proportion of participants received fewer than the recommended three DIALOG+ sessions, limiting the intervention's impact. Clinician workloads, competing priorities and service user disengagement contributed to these gaps.
- **COVID-19 disruptions:** the pandemic created logistical hurdles, with entire clusters lost due to staff redeployment. The shift to remote delivery was implemented without prior feasibility testing, introducing variability in fidelity and participant experiences.
- **Measurement and outcome variability:** the intervention's marginal effects on QoL scores highlight the difficulty of achieving meaningful change in a population with entrenched challenges. Moreover, some participants reported a disconnect between standardised metrics like MANSA and their lived experiences.
- **Technology barriers:** while the use of tablets provided a shared reference point, some participants found it depersonalising, and technical challenges occasionally detracted from the therapeutic interaction.

Reflecting on these challenges highlights the complexities of implementing and evaluating psychosocial interventions in real-world clinical settings, particularly for populations with severe and chronic mental health conditions. Despite these hurdles, the programme's achievements provide a strong foundation for refinement and broader application.

Equality, diversity and inclusion

The TACK programme took deliberate steps to ensure inclusion and diversity, reflecting its commitment to addressing systemic inequities. Recruitment across urban and rural NHS sites captured a range of socioeconomic and demographic backgrounds. The inclusion of the LEAP ensured that the perspectives of individuals with chronic depression informed

every stage of the programme, from design to implementation. This participatory approach enriched the intervention's relevance and acceptability. However, the eligibility criteria requiring English proficiency and access to routine NHS services may have inadvertently excluded certain populations, including non-English speakers, migrants and those disengaged from formal care. Addressing these gaps in future studies could ensure broader applicability and equity.

Strengths and limitations of programme overall

Like all programmes of research, TACK had both strengths and limitations. The pragmatic approach to the TACK RCT, as well as the whole programme, was a key strength regarding the generalisability and reliability of the findings. The study team tested the effectiveness of DIALOG+ for people with chronic depression in services and settings that reflect how it is used currently, or how it would be used if it were to be rolled out more widely within the NHS. The staff training study (WP6) tested how staff and services who were interested in using DIALOG+ could be trained using existing resources to expand the reach of the intervention and improve implementation.

However, the increasing usage of DIALOG+ across mental health services in the UK, particularly NHS England, presented several challenges across the programme. The TACK programme was undertaken during a period where there was increasing recognition and implementation of DIALOG+ following on from the success of the original trial for people with psychosis.[6,7] NHS Trusts were often using DIALOG+ in community care across diagnoses, including for people with long-term depression or related conditions. This meant it was often difficult to recruit teams or services that were not using, or at least not familiar, with the intervention. Our pragmatic approach did not want to pause this roll-out in those trusts, so we had to find study sites that were not using DIALOG+, or find ways to conduct the trial alongside this implementation work (i.e. finding specific clinical teams that were not part of roll-out). Further, the study team were able to support trusts in their roll-out by offering expertise, guidance and resources to ensure the successful implementation of the intervention.

This led to a further strength of the programme which is that the findings from the programme come from a broad range of different NHS Trusts – comprising urban, rural and semi-rural areas. Originally, it was planned to use just four NHS Trusts throughout the whole programme, but because of the increasing use of DIALOG+, the study team had to cultivate more far-reaching research networks, with over 10 NHS Trusts being involved across the six TACK WPs. Additionally, findings come from various service settings, not just CMHTs, for example, intermediary services and primary care services. This means that the findings are widely generalisable.

The programme also made use of a variety of methods, including experimental trial designs, qualitative explorations, surveys and systematic reviews. This mixed-methods approach enabled the study team to provide a rich variety of evidence and obtain different perspectives to build a comprehensive understanding of how DIALOG+ works for people with long-term depression and the clinicians who utilise it. This was in combination with our in-depth involvement activities with the TACK LEAP. PPI was at the heart of all research activities across the programme and the lived experience perspective helped to shape the design of the programme and ultimately the results.

A limitation, however, was the core exclusion criteria used throughout the programme meant that patients who had an insufficient command of English to engage with talking therapy or those who had other difficulties with communication could not be included in the programme. It is unclear how, or if, DIALOG+ could work for people who require translators or other forms of communication support when receiving community mental health care.

As outlined previously, the COVID-19 pandemic made recruitment after 2020 more challenging due to staff and services having more considerations and demands on their time when considering participation. Recruitment to the trial took much longer than originally envisaged, and ultimately, we did not reach the revised target sample size of 376 service-user participants (the trial had a 97.3% recruitment rate). We did, however, demonstrate fairly good follow-up rates at 6 and 12 months (76% and 73%, respectively) and we did gather primary outcome data on a sufficient number of participants to answer the main research question.

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Changes to the programme due to COVID-19

The main TACK trial was launched in June 2019 and was therefore actively recruiting and delivering the intervention in 2020 when the COVID-19 pandemic started. There were a number of changes to the programme that occurred as a result of COVID-19 and the associated social distancing policies that were in place. All research activities were suspended by the National Institute for Health and Care Research in March 2020, and therefore, we were unable to recruit new participants or open new recruiting sites between March and September 2020.

The COVID-19 pandemic had a huge impact on NHS staff and resources, and there were big changes in the organisation and allocation of secondary mental health services during this period, where the TACK trial was primarily recruiting from. Many patients were discharged from their CMHTs (making them suddenly ineligible for the trial), and many staff who were involved in the trial were seconded or changed roles. All routine community care appointments also had to be completed remotely or in a socially distanced manner. This meant that we had a large attrition rate in both our clinician sample and patient sample, and this subsequently impacted our recruitment rate. The recruitment period had to be significantly extended as a result.

However, working with the trial sponsor and the Pragmatic Clinical Trials Unit (PCTU), we were able to successfully continue data collection remotely for post-intervention follow-ups (over the phone or videoconferencing software) and to support clinicians to continue delivering DIALOG+ over the phone. For those participants who had been recruited, baselined and randomised but had received no DIALOG+ sessions, it was decided with the Programme Steering Committee to rebaseline these participants at a time when their routine mental health care began again. SOPs were developed with the PCTU to allow for remote data collection, which particularly impacted the observational interview that was conducted as part of the MADRS measure. This proved successful, and the study team was able to shift to a complete remote data collection model for the remainder of the trial. Obtaining consent for new trial participants could also be completed remotely following the development of a trial-specific SOP.

Finally, we worked with the TACK LEAP to develop resources for participants to support them during the pandemic and created new safeguarding processes for researchers to implement during remote data collection (e.g. a well-being check call 1 week after data collection).

Recommendations for future research

- **Peer-led models:** investigate the feasibility and effectiveness of peer-led delivery models, which may enhance engagement and reduce clinician burden.
- **Enhanced engagement strategies:** develop strategies to improve intervention fidelity, such as motivational enhancements, for service users and clinicians or embedding reminders into care pathways.
- **Adaptations for remote delivery:** conduct feasibility and efficacy studies on delivering DIALOG+ remotely, incorporating lessons learned from the COVID-19 adaptations.
- **Long-term impacts:** evaluate sustained effects on QoL, depressive symptoms and healthcare utilisation over periods exceeding 12 months.
- **Inclusive approaches:** expand recruitment to include non-English-speaking participants and those outside traditional care systems by adapting tools and creating culturally sensitive materials.
- **Naturalist cohort study:** as DIALOG+ has been rolled out in routine practice in a number of services, including across London, a naturalist cohort study could assess the long-term impact on the intervention on QoL.

Implications for practice

- **Structured conversations as a therapeutic tool:** DIALOG+ provides a replicable framework that can bring consistency and depth to routine clinician–patient interactions. Its structured approach facilitates goal setting and empowers service users to take an active role in their care.

- **Economic viability:** with low costs (both in absolute terms and in comparison to the control arm) and high probability of being cost-effective compared to active control, DIALOG+ offers an economically sound solution for enhancing mental health care.
- **Flexibility in delivery:** training requirements for clinicians are minimal, making DIALOG+ scalable across diverse NHS settings. However, enhancing adherence to the intervention protocol will be crucial for maximising its benefits.
- **Broadening scope:** the programme's findings highlight the potential for adapting DIALOG+ to other chronic mental health conditions, including anxiety disorders or complex post-traumatic stress disorder, where structured, solution-focused approaches may also prove effective.

Conclusions of the TACKling chronic depression programme

The TACK programme demonstrated that DIALOG+ is a feasible, cost-effective and acceptable intervention for people with chronic depression. It achieved small but potentially meaningful improvements in subjective QoL and was positively received by both service users and clinicians. The intervention's structured approach fostered greater self-reflection, goal setting and collaboration, addressing some of the long-standing challenges in engaging this population. Although the overall effects were small, compared to the scale (DIALOG) alone, the intervention was cheap and easy to administer, both groups improved in QoL, and any improvement in QoL for this population should be considered important.

While challenges such as fidelity, technological barriers and the impact of COVID-19 were evident, the programme highlighted the adaptability of the DIALOG+ framework. Its scalability, minimal training requirements and alignment with patient-centred care principles make it a potential addition to routine mental health care. Future iterations of the intervention should focus on enhancing fidelity, adapting to diverse delivery models and broadening inclusion to ensure its benefits reach a wider population. The evidence base would also benefit from longer-term, naturalistic follow-ups of DIALOG+ in routine clinical practice. The TACK programme lays the groundwork for a routine approach to managing chronic depression within the NHS and beyond.

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Additional information

CRediT contribution statement

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Nick Barber: Formal analysis (equal).

Jackie Hardy: Formal analysis (equal).

Sudhir Shah: Formal analysis (equal).

Minos Katevas: Software (lead).

John Callaghan: Software (supporting).

Other contributions

Nick Barber: PPI.

Jackie Hardy: PPI.

Sudhir Shah: PPI.

Sarah Markham: PPI.

Syeda Tahir: PPI.

Sue Collinson: PPI (lead).

Patient data statement

This work uses data provided by patients and collected by the NHS as part of their care and support. Using patient data is vital to improve health and care for everyone. There is huge potential to make better use of information from people's patient records, to understand more about disease, develop new treatments, monitor safety, and plan NHS services. Patient data should be kept safe and secure, to protect everyone's privacy, and it is important that there are safeguards to make sure that they are stored and used responsibly. Everyone should be able to find out about how patient data are used. #datasaveslives. You can find out more about the background to this citation here: https://understandingpatientdata.org.uk/data-citation

Data-sharing statement

We shall make data available to the scientific community with as few restrictions as feasible while retaining exclusive use until the publication of major outputs. After publication, data access requests should be submitted to the corresponding author for consideration. Access to anonymised data may be granted following review.

Ethics statement

All research conducted as part of the TACK programme was done so in accordance with the World Medical Association Declaration of Helsinki (www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/). The research team sought regular approval from the Health Research Authority (HRA) and adhered to the highest standards of research governance.

Three separate applications for ethical review were made to the NHS Research Ethics Committee/HRA through the programme. These are listed below:

1. NHS REC favourable opinion from Wales Research Ethics Committee 5 for Phase I of the programme, which included the exploratory study (WP2) and the feasibility trial (WP3) was received on 19 March 2017 (17/WA/0085).

2. NHS REC favourable opinion from Wales Research Ethics Committee 6 for Phase II of the programme, which included the main trial (WP4) and the process evaluation (WP5) was received on 20 May 2019 (19/WA/0160).

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3. HRA approval for the Training Study (WP6). Approval received on 3 April 2023 (23/HRA/0805).

Information governance statement

East London NHS Foundation Trust is committed to handling all personal information in line with the UK Data Protection Act (2018) and the General Data Protection Regulation (EU GDPR) 2016/679. Under the Data Protection legislation, East London NHS Foundation Trust is the Data Controller, and you can find out more about how we handle personal data, including how to exercise your individual right here: www.elft.nhs.uk/information-about-elft/privacy-and-your-data or by directly contacting the ELFT Data Protection Officer on elft.dpo@nhs.net or by calling 020 7655 4000.

Disclosure of interests

Full disclosure of interests: Completed ICMJE forms for all authors, including all related interests, are available in the toolkit on the NIHR Journals Library report publication page at https://doi.org/10.3310/GJVB1014.

Primary conflicts of interest: We endeavour to obtain ICMJE disclosure of interests forms for all named authors. In this case, we have been unable to obtain these forms for every author. Please contact the corresponding author if you have any queries. No conflicts of interest are declared.

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Publications

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Publications currently in press

Assefa E, Priebe S, Bird V, Feng Y. Assessing psychometric properties of EQ-5D-5L and ICECAP-A in patients with chronic depression in England. *Health Qual Life Outcomes*.

Dissemination events

Activity title	Advanced training for NHS Wales staff
Activity type	Event, workshop or similar
How many people?	11–50
Geographical reach	National
Primary audience	Professional practitioners
Other audience	Policy-makers/politicians
Activity year	2020
Result description	As part of the collaboration with NHS Wales '1000 Lives Plus' project, the TACK research team were asked to design and deliver some advanced training for the clinicians using DIALOG+ within their teams and services. This training was asked to focus specifically on the implementational barriers of DIALOG+ so as to facilitate uptake and increase clinician confidence in its use. The training was made up of three separate training workshops, each lasting 2 hours
Most important impact	Audience reported change in views, opinions or behaviours

Activity title	Centre for Primary Care and Public Health seminar
Activity type	A talk or presentation or debate
How many people?	11–50
Geographical reach	Local
Primary audience	Other audiences
Other audience	Professional practitioners, postgraduate students
Activity year	2019
Result description	A seminar presentation was given on 9 January 2019 at the Centre for Primary Care and Public Health monthly seminar series. This involved discussing the ongoing results of the development and piloting work (WP2) as well as discussing the potential for future collaborations, particularly within primary care. The event was aimed at academics and general practitioners. The talk was a collaboration between the NIHR programme Grant (TACK) and a Barts-funded PhD assessing the use of DIALOG+ in primary care
Most important impact	Requests about (further) participation or involvement

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Activity title	Conference Oral Presentation at ENMESH 2019
Activity type	A talk or presentation or debate
How many people?	51–100
Geographical reach	International
Primary audience	Professional practitioners
Other audience	Policy-makers/politicians, professional practitioners, postgraduate students, patients, carers and/or patient groups
Activity year	2019
Result description	The oral presentation, outlining the DIALOG+ intervention and associated research activities, was presented as part of a symposium at the ENMESH conference. The symposium was well attended (> 50 delegates) and prompted debate around solution-focused and patient-centred models of care within national mental healthcare systems. The presenter was later approached by a number of international delegates who were interested in collaborating in order to test the DIALOG+ intervention within their settings
Most important impact	Plans made for future related activity
URL	https://enmesh.eu/ENMESH%202019%20Abstract%20Book.pdf
Activity title	DIALOG+ presentation at Luton research showcase
Activity type	A talk or presentation or debate
How many people?	11–50
Geographical reach	Regional
Primary audience	Professional practitioners
Other audience	Professional practitioners, study participants or study members, patients, carers and/or patient groups
Activity year	2019
Result description	A presentation was given as part of a research showcase organised by ELFT in Luton. This was to encourage patients and staff to get involved in ongoing research initiatives happening within the area, and to report on the research findings of the projects so far. DIALOG+ was presented, including the initial findings of Phase 1. From the event, staff members and patients contacted us about involvement in the research and/or advisory panels
Most important impact	Requests about (further) participation or involvement
Activity title	Early Intervention in Psychosis – All Wales Virtual Conference
Activity type	A talk or presentation or debate
How many people?	101–500
Geographical reach	National
Primary audience	Professional practitioners
Other audience	Policy-makers/politicians, study participants or study members, patients, carers and/or patient groups, third-sector organisations
Activity year	2024
Result description	Programme manager, Philip McNamee, facilitated a presentation called 'Testing and Embedding DIALOG+: Recent results from trial and implementation work' at the All Wales Conference. This was part of evidencing the impact that DIALOG+ has had on clinical services where DIALOG+ has been used and the many ways in which the routinely collected outcome data can be used to improve services and quality of care
Most important impact	Audience reported change in views, opinions or behaviours
URL	https://performanceandimprovement.nhs.wales/functions/quality-safety-and-improvement/improvement/our-work/mental-health/early-intervention-in-psychosis/

Activity title	ELFT Research Day Presentation
Activity type	A talk or presentation or debate
How many people?	101–500
Geographical reach	Local
Primary audience	Professional practitioners
Other audience	Professional practitioners, patients, carers and/or patient groups
Activity year	2019
Result description	Qualitative data from WP2 (development and piloting) of the current award were presented at the ELFT Research Day on 10 October 2018. The presentation was called 'DIALOG+ for chronic conditions in primary care' and presented findings from the exploratory study whereby primary care staff (general practitioners, nurses and healthcare assistants) were asked about their opinions of suitability for DIALOG+ for managing chronic conditions (particularity in depression) within primary care. The data from TACK were combined with some data from a separate but linked study investigating DIALOG+ applied to the management of diabetes in primary care (this was a prime pump study funded by Barts charity)
Most important impact	Requests about (further) participation or involvement

Activity title	ENMESH 2024 Symposium 'Resource-oriented interventions within mental health services: innovations and results from 4 trials'
Activity type	A talk or presentation or debate
How many people?	11–50
Geographical reach	International
Primary audience	Professional practitioners
Other audience	Undergraduate students, postgraduate students, patients, carers and/or patient groups, third-sector organisations
Activity year	2024
Result description	Symposium entitled 'Resource-oriented interventions within mental health services: innovations and results from 4 trials', which was chaired by the programme manager of the TACK trial. The TACK trial results were also presented as part of this symposium. Around 50 people attended the symposium, which led to a wider discussion about resource orientation in mental health services, particularly the cultural differences that exist across European countries
Most important impact	Requests for further information

Activity title	LEAP Members – Qualitative Training
Activity type	A formal working group, expert panel or dialogue
How many people?	1–10
Geographical reach	Local
Primary audience	Patients, carers and/or patient groups
Other audience	No other audiences
Activity years	2018, 2019
Result description	As part of the qualitative analysis from WP2, two expert members of the LEAP were invited to train in qualitative analysis techniques and be part of the analysis team. The two service user researchers attended in-house training on 17 August 2018, where they were introduced to the basics of thematic analysis. The SU researchers were then given pseudonymised transcripts to take away and analyse. The analysis group met again on the 12 October, whereby the preliminary analysis by all analysts was used to create a coding framework that could be applied across transcripts. The analysis was completed over the following months, with a final whole team meeting on 19 March where the final themes and findings section of the paper were confirmed. The LEAP, as whole, were also asked to feedback on the findings at the meeting on 12 February 2019

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Most important impact	Decision made or influenced
Activity title	Lived Experience Advisory Panel
Activity type	A formal working group, expert panel or dialogue
How many people?	1–10
Geographical reach	Local
Primary audience	Patients, carers and/or patient groups
Other audience	No other audiences
Activity years	2017, 2018
Result description	A Lived Experience Advisory Group was created in May 2017, in order to centralise a service user voice in the TACK programme grant. This panel is comprised of six people (experts by experience) who all have experience of being diagnosed and treated for chronic depression or experience of caring for someone with depression. The panel meets between two and three times a year and are involved in ensuring participant-facing documents are appropriately worded, developing bespoke outcome measures for the trial work and contributing to the analysis of the qualitative data. The panel have asked that they are trained in research methods as part of their collaboration and thus training has been developed by the research team for this group
Most important impact	Not aware of any impact
URL	http://tack.elft.nhs.uk/About-us/LEAP
Activity title	NIHR blog-post about the TACK Programme Grant
Activity type	Engagement-focused website, blog or social media channel
How many people?	More than 500
Geographical reach	National
Primary audience	Professional practitioners
Other audience	Policy-makers/politicians, professional practitioners, public/other audiences, other audiences, third-sector organisations
Activity year	2017
Result description	To celebrate World Mental Health Day and to inform a wider audience about the TACK programme grant, NIHR approached the research team and asked them if they could write a blog about the aims of the research. This involved gaining a quote from the programme manager about the importance of the research and describing the planned work. The blog post resulted in interest from service users and fellow researchers about the project
Most important impact	Requests for further information
URL	www.nihr.ac.uk/news/tackling-depression-a-new-approach/7036
Activity title	Oral Conference Presentation at 20th Congress of the European Psychiatric Association Section of Epidemiology and Social Psychiatry
Activity type	Event, workshop or similar
How many people?	11–50
Geographical reach	International
Primary audience	Professional practitioners
Other audience	Postgraduate students, patients, carers and/or patient groups
Activity year	2022
Result description	Lauren Jerome, one of the research assistants on the TACK programme, presented an oral presentation titled 'A solution-focused approach (DIALOG+) to improve quality of life for people with chronic depression: findings from a feasibility trial'. This was at the 20th Congress of the European Psychiatric Association Section of Epidemiology and Social Psychiatry held in Cambridge in September 2022
Most important impact	Requests for further information

Activity title	Presentation and Work with the Trust Board at Norfolk and Suffolk Foundation Trust
Activity type	A formal working group, expert panel or dialogue
How many people?	11–50
Geographical reach	Regional
Primary audience	Professional practitioners
Other audience	Professional practitioners, patients, carers and/or patient groups
Activity year	2017
Result description	Following initial contact with a member of the Trust board for Norfolk and Suffolk NHS Foundation Trust which occurred after a presentation on DIALOG+ within London, I was invited to attend a panel meeting of commissioners, Trust board members, practitioners and service users to discuss the possibilities for using DIALOG+ within the Trust. Following this successful meeting, further contact and visits have been made and the Trust are listed as a potential site for the trial, should we encounter any issues with recruitment
Most important impact	Requests about (further) participation or involvement

Activity title	Presentation at the fourth European Congress on Assertive Outreach – Hamburg
Activity type	A talk or presentation or debate
How many people?	51–100
Geographical reach	International
Primary audience	Professional practitioners
Other audience	Professional practitioners, postgraduate students, patients, carers and/or patient groups
Activity year	2017
Result description	Conference presentation to a professional and service user audience at the fourth European Congress on Assertive Outreach. The presentation focused on the initial piloting of DIALOG+ and plans for future work
Most important impact	Requests for further information

Activity title	Presentation at the Society for Academic Primary Care South East Regional Conference 2019
Activity type	A talk or presentation or debate
How many people?	101–500
Geographical reach	National
Primary audience	Professional practitioners
Other audience	Policy-makers/politicians, professional practitioners, postgraduate students, patients, carers and/or patient groups
Activity year	2019
Result description	A presentation was given at the Society for Academic Primary Care South East Regional Conference 2019, Madingley Hall, Cambridge. The presentation focused on the results of the initial stages of the programme and discussed the involvement and potential for the use of DIALOG+ in primary care
Most important impact	Requests about (further) participation or involvement

Activity title	Presentation of DIALOG+ intervention and TACK programme grant progress at First Episode Psychosis Conference, NHS Wales 1000 Lives Improvement
Activity type	A talk or presentation or debate
How many people?	51–100
Geographical reach	National
Primary audience	Professional practitioners

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Other audience	Policy-makers/politicians, supporters, patients, carers and/or patient groups, third-sector organisations
Activity year	2017
Result description	The TACK team were approached by 1000 Lives Improvement, NHS Wales, and were invited to present at the annual First Episode Psychosis Conference, Cardiff (18 October 2017). The purpose of this event was to discuss and present novel and effective interventions for first episodes of psychosis and how NHS Wales can adopt some of these practices in their mental health care. The team also took this opportunity to present the preliminary work of the TACK programme grant and show how the DIALOG+ intervention is planning to be applied across mental health conditions, particularly chronic depression
Most important impact	Requests about (further) participation or involvement

Activity title	Presentation of the TACK programme grant to the ASK Forum
Activity type	A formal working group, expert panel or dialogue
How many people?	11–50
Geographical reach	Local
Primary audience	Patients, carers and/or patient groups
Other audience	No other audiences
Activity year	2017
Result description	The programme manager presented the project to the ASK Forum (a local patient public engagement project for mental health service users in the Newham area). This was to raise awareness of the type of research being conducted by the local NHS Trust and to boost the profile of the DIALOG+ intervention. There was a great deal of interest from local service users which led to an increase in interest to participate and learn more about DIALOG+
Most important impact	Requests about (further) participation or involvement

Activity title	Regular seminars presenting the progress of DIALOG+ at the Unit for Social and Community Psychiatry (QMUL)
Activity type	A talk or presentation or debate
How many people?	11–50
Geographical reach	Regional
Primary audience	Other audiences
Other audience	Patients, carers and/or patient groups
Activity year	2018
Result description	Public seminars are presented every Monday at 2 p.m. within the Unit for Social and Community Psychiatry to update interested parties about the current research happening within the Unit. As part of this seminar series, the TACK study has been presented numerous times by all members of the research team. One of these seminars attracted a service user representative from the Norfolk and Suffolk NHS Foundation Trust, who was interested in how the DIALOG+ intervention could be implemented within her own Trust's services. This has led to ongoing correspondence
Most important impact	Plans made for future related activity
URL	www.elft.nhs.uk/Research/What-We-Do/Seminars--Training

Activity title	Symposium at the World Psychiatric Association Thematic Congress, Melbourne, 2018
Activity type	A talk or presentation or debate
How many people?	11–50
Geographical reach	International
Primary audience	Other audiences

Other audience	Professional practitioners, postgraduate students, patients, carers and/or patient groups
Activity year	2018
Result description	A symposium chaired by Dr Victoria Bird (Chief Investigator of the TACK programme grant) called 'Resource orientation a global perspective' with a specific talk about the research called 'Finding solutions not problems – DIALOG+'. The symposium led to additional research and network meetings with Australia-based researchers who were interested in future projects that applied DIALOG+ to healthcare systems in Australia
Most important impact	Plans made for future related activity

Activity title	Symposium at the WPA World Congress of Psychiatry, Berlin, 2017
Activity type	A talk or presentation or debate
How many people?	11–50
Geographical reach	International
Primary audience	Professional practitioners
Other audience	Professional practitioners, undergraduate students, postgraduate students, third-sector organisations
Activity year	2017
Result description	A symposium as part of the World Psychiatric Association's World Congress of Psychiatry (Berlin 2017), titled 'Resource orientation in psychiatry: it is not just what you have got but also how you use it', was chaired by the cochief investigators of the TACK programme Dr Victoria Bird and Prof Stefan Priebe. As part of this symposium, Dr Bird presented a talk, entitled 'Improving quality of life through solutions not problems-DIALOG+', in which the aims and objectives of the TACK research programme were presented. The purpose of this presentation was to increase the profile of the DIALOG+ intervention and show its application to multiple conditions. This led to requests for further information by numerous interested parties
Most important impact	Requests for further information

Activity title	TACK/PIECEs International Lived Experience Advisory Panel Exchange
Activity type	Event, workshop or similar
How many people?	11–50
Geographical reach	International
Primary audience	Patients, carers and/or patient groups
Other audience	Professional practitioners
Activity year	2023
Result description	This meeting was an ambitious attempt to exchange learning about the best methods to involve people with SMI into research activities. Taking two established Lived Experience Advisory Panels (one from the TACK programme based in the UK, and another from the PIECEs study based in India and Pakistan), the aim was to understand how we can better support coproduction and co-design in these differing contexts and how we can exchange best practise to ensure involvement is not tokenistic or replicates poor methods
Most important impact	Plans made for future-related activity

Activity title	TACK Feasibility Trial Presentation at ELFT Research Day
Activity type	Event, workshop or similar
How many people?	51–100
Geographical reach	Local
Primary audience	Professional practitioners
Other audience	Postgraduate students, study participants or study members, patients, carers and/or patient groups, third-sector organisations
Activity year	2022

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Result description	The TACK feasibility trial mixed-methods results were presented to a large audience as part of the ELFT Research Day. This is an annual event that showcases the research that has taken place within, or is co-ordinated by, ELFT to a mixed group of clinicians, local charities, students and the general public; as well as being in person, the presentation was also broadcast live
Most important impact	Requests about (further) participation or involvement

Activity title	TACK/PIECEs Advisory Meeting
Activity type	A formal working group, expert panel or dialogue
How many people?	11–50
Geographical reach	International
Primary audience	Professional practitioners
Other audience	Professional practitioners, patients, carers and/or patient groups
Activity year	2021
Result description	The PIECEs project is testing the use of DIALOG+ with patients with psychosis in India and Pakistan. As part of this project, the local researchers were interested in how best to involve service users and carers in the project and to ensure their involvement activities were meaningful. The TACK researchers organised an international advisory meeting, whereby members of the TACK Lived Experience Advisory Panel, who all have experience of involvement activities, advised the researchers in India and
Most important impact	Audience reported change in views, opinions or behaviours

Activity title	Talk provided to Transformation Care Model Group
Activity type	A talk or presentation or debate
How many people?	11–50
Geographical reach	Local
Primary audience	Professional practitioners
Other audience	Professional practitioners
Activity year	2020
Result description	A talk on the secondary data analysis completed by the PhD student was given to the members of the ELFT Transformation CAre Model and Outcomes group. The talk discussed how DIALOG+ had been used and analysed within the Trust and the implications of this going forward, when planning new models of primary and secondary mental health care
Most important impact	Plans made for future-related activity

Activity title	Training Clinical Staff in Wales (1000 Lives Project)
Activity type	Event, workshop or similar
How many people?	11–50
Geographical reach	National
Primary audience	Professional practitioners
Other audience	Policy-makers/politicians, patients, carers and/or patient groups
Activity year	2019
Result description	As part of the 1000 lives matter initiative (and collaboration), an all-day training workshop and seminar was held in September 2019 in Cardiff. Representatives from CMHTs and inpatient services across Wales attended the training and implementation workshop. Discussions were had about the best way to implement DIALOG and DIALOG+ within routine care. This enables the research team to gain feedback on the training materials and approaches to training as well as consider what will be required if wider implementation is going to occur beyond the TACK trial
Most important impact	Plans made for future-related activity

Activity title	Training in Qualitative Methods for the Members of the PPI Group
Activity type	Event, workshop or similar
How many people?	1–10
Geographical reach	Local
Primary audience	Patients, carers and/or patient groups
Other audience	Patients, carers and/or patient groups
Activity years	2021, 2022
Result description	Members of the TACK Lived Experience Advisory Panel were trained in thematic analysis (an approach to analyse qualitative data) on the following dates: 25 June 2021 (1.5 hours), 1 October 2021 (1 hour) and 10 December 2021 (1.5 hours). This was part of a wider goal of the TACK programme to equip the LEAP members with research skills that they could use both as part of this study and also in the future with other studies. The four attendees gained a thorough understanding of how to use thematic analysis as part of an analytic group and are currently analysing data that came from the TACK feasibility trial and which will be published this year
Most important impact	Requests about (further) participation or involvement

Activity title	UKRCOMs Presentation
Activity type	A talk or presentation or debate
How many people?	11–50
Geographical reach	National
Primary audience	Professional practitioners
Other audience	Policy-makers/politicians, patients, carers and/or patient groups
Activity years	2018, 2019
Result description	A presentation about the updated DIALOG+ was given at a UKRCOMs meeting which focuses on improving patient reported outcomes and care planning in mental health care. This generated interest in the project, including trusts requesting to be part of the larger WP4 trial. Trusts are very interested in the results of the trial, as QoL was highlighted as a particular issues for patients with chronic depression
Most important impact	Requests about (further) participation or involvement

Activity title	William Harvey Day Presentation
Activity type	A talk or presentation or debate
How many people?	101–500
Geographical reach	Local
Primary audience	Professional practitioners
Other audience	Professional practitioners, public/other audiences, supporters, undergraduate students, postgraduate students
Activity year	2019
Result description	Invited presentation given at William Harvey Day (QMUL). The presentation gave an overview of DIALOG+ and the TACK programme to practitioners, faculty members and students. The primary aim was to give information about the programme and encourage wider participation
Most important impact	Requests about (further) participation or involvement

Activity title	Working Collaboration with Influential Users of Social Media
Activity type	Engagement focused website, blog or social media channel
How many people?	101–500

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Geographical reach	International
Primary audience	Patients, carers and/or patient groups
Other audience	Media (as a channel to the public), policy-makers/politicians, professional practitioners, public/other audiences, study participants or study members, patients, carers and/or patient groups, third-sector organisations
Activity year	2019
Result description	A team member (research assistant) has been working collaboratively with mental health blog 'The Mental Elf' to support tweeting and blogging of mental health-related information and conferences, including the MQ Science Meeting on 7 and 8 February. We are currently working together to write a blog about the development of DIALOG+ within this programme and to ensure that our research is picked up by influential social media users to ensure it reaches a wide target audience
Most important impact	Plans made for future-related activity

Activity title	World Association of Social Psychiatry and Royal College of Psychiatrists Annual Congress- Symposium
Activity type	A formal working group, expert panel or dialogue
How many people?	101–500
Geographical reach	International
Primary audience	Professional practitioners
Other audience	Postgraduate students, other audiences, patients, carers and/or patient groups, third-sector organisations
Activity year	2023
Result description	The programme manager of TACK (along with a service user researcher from the TACK Lived Experience Advisory Panel) copresented the involvement activities that have occurred within TACK as part of a Symposium at the Annual Congress of WASP and RC Psychiatrists. The symposium was called 'Developing and testing interventions to transform mental health care together with patients and carers'
Most important impact	Requests about (further) participation or involvement
URL	https://waspsocialpsychiatry.org/report-of-wasp-world-congress-2023-london-16-18-january-2023/

Activity title	Barnet, Enfield and Haringey NHS Mental Health Trust/Inclusion Barnet Research Project
Activity type	A formal working group, expert panel or dialogue
How many people?	11–50
Geographical reach	Local
Primary audience	Third-sector organisations
Other audience	Policy-makers/politicians, professional practitioners, public/other audiences, third-sector organisations
Activity year	2019
Result description	Providing consultation on this project between the NHS Trust and the local third-sector organisation (a peer-led deaf and disabled people's organisation that uses lived experience to enhance and improve services) to pilot DIALOG+ (as developed in the award) as the electronic Care Programme Approach in two inpatient wards. The intervention will be delivered by peer support workers regularly, using DIALOG+ embedded in RiO to improve care plans, risk assessments and treatment goals. As part of the consultation process, I have presented DIALOG+ to senior managers of the trust (from a range of departments, e.g. IT, clinical services and PPI) and Inclusion Barnet staff and trained clinical staff on the wards who will be overseeing the delivery of the intervention within the pilot scheme. This is part of the wider roll-out of DIALOG+ in BEH which links with the London-wide DIALOG+ implementation group and to participation in the feasibility and main trial components of the award
Most important impact	Decision made or influenced

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Appendix 1 The Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow chart for work package 1 systematic review

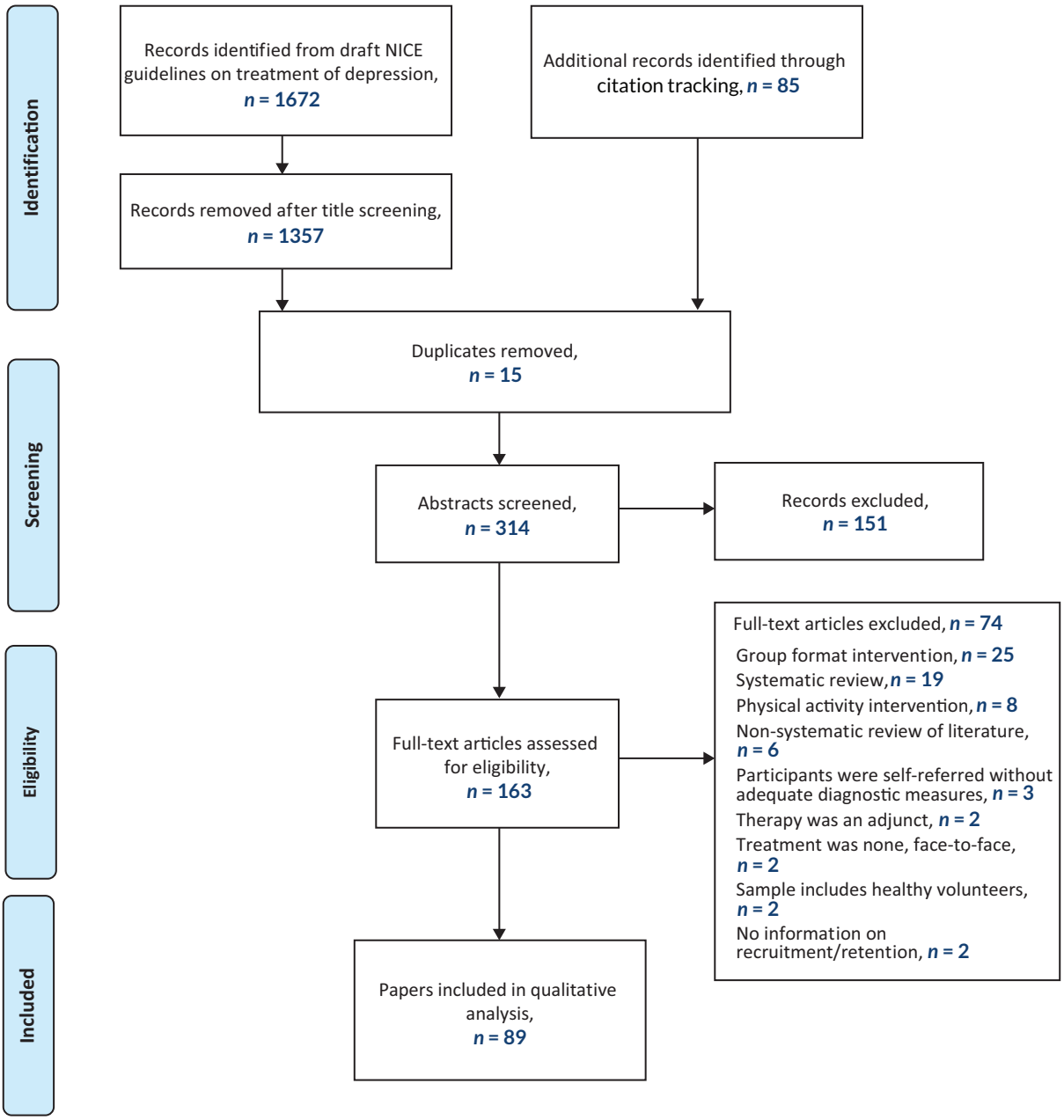

FIGURE 2 Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow diagram.

Appendix 2 Consolidated Standards of Reporting Trials flow diagram for cluster randomised controlled trial (work package 4)

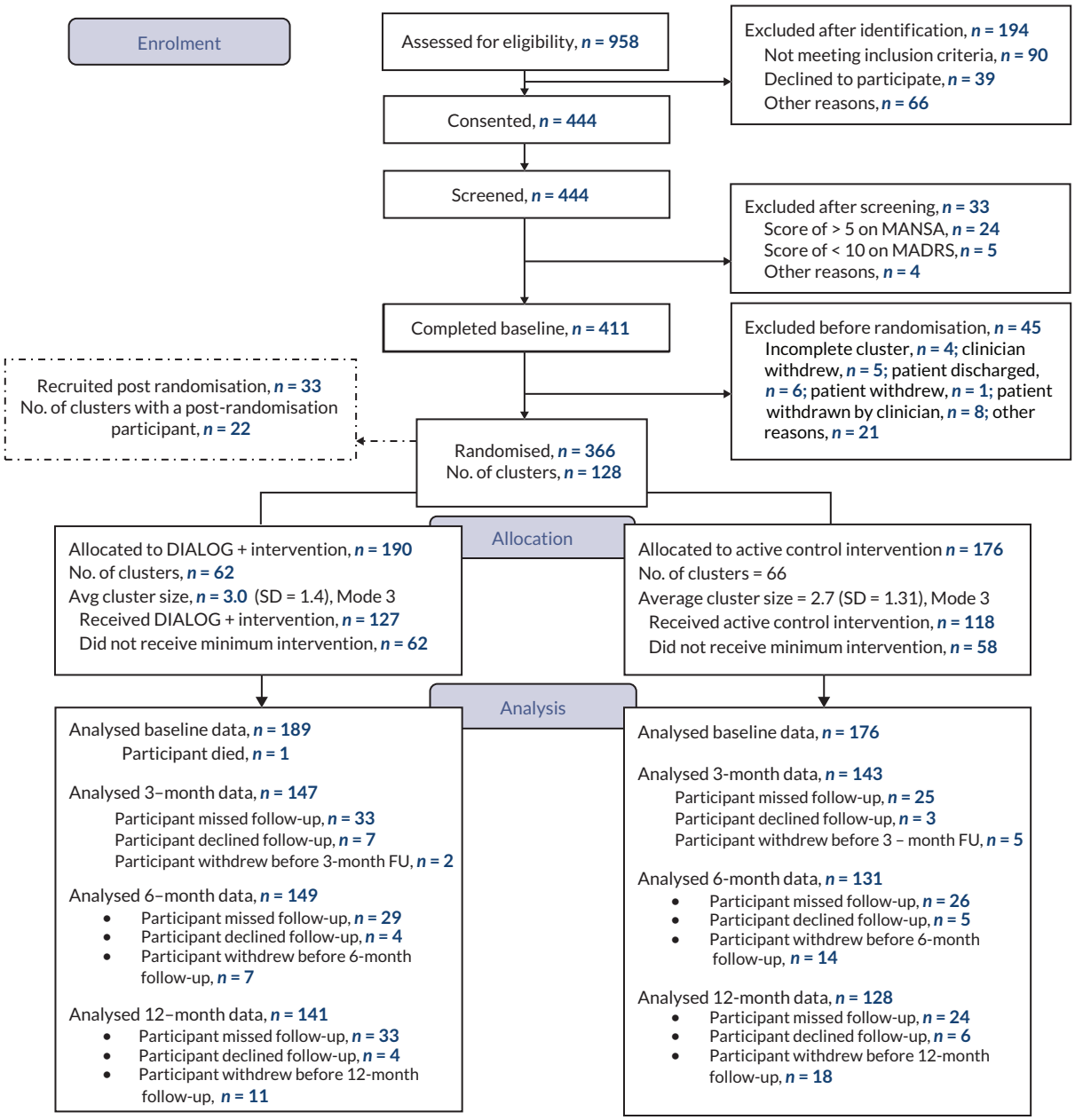

FIGURE 3 The TACK cRCT CONSORT flow diagram.

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Appendix 3 Statistical methods for the analysis of trial data

General analysis principles

The primary outcome (MANSA score at 12 months) was analysed using a mixed-effects linear regression model with Gaussian error. In addition to treatment arm (fixed effect; intervention arm vs. control arm), the following covariates were included for statistical adjustment: baseline MANSA score, site (both as fixed effects) and clinician (random effect as an intercept). To supplement the main MANSA analysis, data are presented on response rate to questions 4, 5, 9 and 10 from the MANSA schedule at 12 months in addition to estimated treatment difference expressed as an odds ratio, associated 95% CI and *p*-value (analysis; mixed-effects logistic regression using the same model specification as for the primary analysis).

All secondary outcomes were analysed following the same specification, albeit with baseline measure chosen to reflect the outcome in question (e.g. baseline MADRS for analysis of MADRS at study completion).

Secondary analysis

In order to assess the robustness of the primary result to possible influence of 'nuisance' factors, the MANSA analysis was repeated, including, in addition to the original specification, the following list of covariates: age, gender, marital status, ethnicity, educational attainment, employment status, diagnosis category, NHS Trust, baseline outcome score (MANSA where post-baseline MANSA-score is outcome, MADRS where MADRS-score is outcome, etc.). Imputation of covariates was invoked as a back-up to substantiate analysis in the event of > 5% of participants with a valid outcome being discarded from the initial complete-case analysis through missing data.

Sensitivity analysis

Sensitivity analyses were conducted with respect to the main analysis for: (1) the primary outcome of MANSA at 12 months and (2) the following secondary outcomes: MADRS and BDI-II at 12 months to assess the impact of missing data under reasonable assumptions about the behaviour of those lost to follow-up. Missing outcomes were imputed based on select characteristics (age, gender, ethnicity, language, education level, marital status, type of accommodation, diagnostic codes and employment status), including the same outcome at earlier time points, with a random component based on model error using the 'mi impute' command in Stata.[33] The primary analysis was rerun on the resulting data set and this was repeated over a number of similarly imputed data sets (N = 50), with results averaged according to a multiple imputation approach.[34] Results and estimates from sensitivity analysis were compared against those from the primary analysis to ascertain the impact (if any) of loss to follow-up in this study. To supplement this analysis, the breakdown of demographic variables is reported for the subgroup missing from analysis at 12 months for comparison with the overall study population.

Mediation analysis

Mediation analysis[35] was carried out on the primary outcome to assess whether putative treatment effect on QoL at 12 months (MANSA) is mediated through a reduction in depression scores at 6 months, using the SEM procedure in Stata. This involved developing a model that specifies the relationship in terms of a pathway between the treatment, depression and QoL variables and then testing whether the model fits the observed data. Two separate models were run, one where depression was defined on the MADRS scale and the other on BDI-II scale.

Per-protocol analysis

To assess the treatment effect under conditions of treatment fidelity, a per-protocol analysis was carried out on MANSA scores, using the same methods as the main analysis but including only those participants who received three or more DIALOG+ sessions or control sessions, respectively. At least two repeat sessions over the 12 months are considered essential to capture the key elements of the intervention.

Longitudinal analysis

To address potential bias due to attrition and subsequent missing data, a linear mixed-effects model was conducted, with MANSA scores at all time points as the dependent variable. The model included a random effect for site and, within site clusters, cross-classified random effects of time and patient.

Mode-of-delivery analysis

The main analysis was revisited with the refinement that an effect for mode of delivery of treatment [three categories: face-to-face, remote (online or over the phone) or mixed] was included in addition to the interaction between mode of delivery and treatment. If the interaction term proved to be non-significant, the default approach was to fit and report the model, including main effects only. This analysis was motivated by an anticipated change in the nature of intervention delivery in response to lockdown restrictions in response to the COVID-19 pandemic.

Assessment of blinding

A chi-squared test was carried out to compare the assessment of blinding, that is blinded researcher guessing the correct treatment group at point of data collection versus correctly guessing the allocation by chance (50%).

Serious adverse events

The number of (1) SAEs (2) participants experiencing at least one SAE is presented by treatment arm for all patient participants.

Serious adverse events are also presented in the following subcategories by treatment arm (1) death, (2) admission to inpatient ward and (3) other important medical event. Where there was an admission to an inpatient unit, this is divided by whether this was to an acute hospital ward or a psychiatric ward based on the ‘free-text’ data available.

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Appendix 4 Statistical results tables and figures

TABLE 10 Baseline characteristics of participants randomised in the TACK trial

Participants demographics	Summary measure	
	Active control no. (%)	Intervention no. (%)
Age (years); mean (SD)	47.6 (15.3)	45.9 (15.1)
Gender; N (%)		
Female	112 (63.6)	125 (66.1)
Male	63 (35.8)	63 (33.3)
Other	1 (0.6)	1 (0.5)
Marital status; N (%)		
Single/unmarried	79 (44.9)	101 (53.4)
Married/cohabiting/civil partnership	60 (34.1)	48 (25.4)
Separated/divorced	28 (15.9)	32 (16.9)
Widow/widower	9 (5.1)	8 (4.2)
Ethnicity; *N* (%)		
Asian/Asian British	1 (0.6)	3 (1.6)
Black/African/Caribbean/Black British	2 (1.1)	5 (2.6)
Mixed/multiple ethnic groups	4 (2.3)	7 (3.7)
White/White Irish/White other	163 (93.1)	171 (90.5)
Other	5 (2.9)	3 (1.6)
First language; N (%)		
English	171 (97.2)	183 (96.8)
Other	5 (2.8)	6 (3.2)
Education attainment; N (%)		
Primary education (or less)	11 (6.3)	10 (5.3)
Secondary education	50 (28.4)	58 (30.7)
Tertiary/further education	59 (33.5)	65 (34.4)
Higher education (e.g. university)	51 (29.0)	52 (27.5)
Other general education	5 (2.8)	4 (2.1)
Employment status; N (%)		
Paid/self-employed (full-time)	24 (13.6)	20 (10.6)
Paid/self-employed (part-time)	17 (9.7)	14 (7.4)

TABLE 10 Baseline characteristics of participants randomised in the TACK trial (*continued*)

Participants demographics	Summary measure	
	Active control no. (%)	Intervention no. (%)
Voluntary	6 (3.4)	7 (3.7)
Sheltered	1 (0.6)	0 (0.0)
Unemployed	78 (44.3)	94 (49.7)
Student	3 (1.7)	9 (4.8)
Housewife/husband	11 (6.3)	7 (3.7)
Retired	28 (15.9)	31 (16.4)
Other	8 (4.5)	7 (3.7)
Receiving state benefit?; N (%)		
No	42 (23.9)	44 (23.3)
Yes	134 (76.1)	145 (76.7)
Accommodation; N (%)		
Independent	152 (86.4)	170 (89.9)
Supported	17 (9.7)	9 (4.8)
Homeless/roofless	0 (0.0)	1 (0.5)
Other	7 (4.0)	9 (4.8)
Main diagnosis (ICD-10 code); N (%)		
F10–F19	0 (0.0)	2 (1.1)
F20–F29	13 (8.1)	15 (8.3)
F30–F39	61 (37.9)	72 (40.0)
F40–F48	28 (17.4)	29 (16.1)
F50	1 (0.6)	0 (0.0)
F60–F69	21 (13.0)	34 (18.9)
F80–F89	1 (0.6)	3 (1.7)
F90–F98	1 (0.6)	0 (0.0)
F99	0 (0.0)	1 (0.6)
Other	35 (21.7)	24 (13.3)
Service type; N (%)		
Primary care	84 (47.7)	72 (38.1)
Secondary care	156 (88.6)	165 (87.3)
Social services	4 (2.3)	6 (3.2)
Other	5 (2.8)	3 (1.6)

ICD-10, *International Statistical Classification of Diseases and Related Health Problems*, Tenth Revision.

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TABLE 11 Number and percentage of participants answering 'yes' to four yes/no items on the MANSA scale at 12 months by treatment group; odds ratio, CIs and *p*-values presented from mixed-effects logistic regression adjusting for baseline answer, site and clinician

MANSA item	*n*/*N* (%); *n* = number who responded 'yes', *N* = number who answered question		Odds ratio (95% CI)	*p*-value
	DIALOG+	Active control		
Q4 – Do you have someone you would call a close friend?	106/141 (75.2)	85/128 (66.4)	2.10 (1.04 to 4.23)	0.04
Q5 – In the last week, have you seen a friend?	86/141 (61.0)	67/128 (52.3)	1.42 (0.84 to 2.41)	0.19
Q9 – In the past year, have you been accused of a crime?	2/141 (1.4)	2/128 (1.6)	0.84 (0.04 to 19.52)	0.91
Q10 – In the past year, have you been a victim of physical violence?	9/140 (6.4)	6/128 (4.7)	1.84 (0.55 to 6.24)	0.32

TABLE 12 Baseline characteristics of participants allocated to a treatment arm in TACK study

Participants demographics	Summary measure	
	Active control no. (%), *N* = 48	Intervention no. (%), *N* = 48
Age (years); mean (SD)	44.4 (14.7)	40.3 (14.2)
Gender; N (%)		
Female	31 (64.6)	33 (68.8)
Male	17 (36.2)	15 (30.6)
Other		
Marital status; N (%)		
Single/unmarried	25 (52.1)	33 (68.8)
Married/cohabiting/civil partnership	13 (27.1)	12 (25.0)
Separated/divorced	8 (16.7)	3 (6.3)
Widow/widower	2 (4.2)	0 (0.0)
Ethnicity; N (%)		
Asian/Asian British	1 (2.1)	0 (0.0)
Black/African/Caribbean/Black British	0 (0.0)	1 (2.1)
Mixed/multiple ethnic groups	2 (4.2)	4 (8.3)
White/White Irish/White other	43 (89.6)	43 (89.6)
Other	2 (4.2)	0 (0.0)
First language; N (%)		
English	47 (97.9)	47 (97.9)
Other	1 (2.1)	1 (2.1)
Education attainment; N (%)		
Primary education (or less)	3 (6.3)	3 (6.3)
Secondary education	18 (37.5)	17 (35.4)
Tertiary/further education	13 (27.1)	13 (27.1)

TABLE 12 Baseline characteristics of participants allocated to a treatment arm in TACK study (*continued*)

	Summary measure	
Participants demographics	**Active control no. (%), *N* = 48**	**Intervention no. (%), *N* = 48**
Higher education (e.g. university)	12 (25.0)	13 (27.1)
Other general education	2 (4.2)	2 (4.2)
Employment status; N (%)		
Paid/self-employed (full-time)	9 (18.8)	5 (10.4)
Paid/self-employed (part-time)	6 (12.5)	3 (6.3)
Voluntary	0 (0.0)	2 (4.2)
Unemployed	21 (43.8)	32 (66.7)
Student	0 (0.0)	2 (4.2)
Housewife/husband	3 (6.3)	1 (2.1)
Retired	4 (8.3)	2 (4.2)
Other	5 (10.4)	1 (2.1)
Receiving state benefit? N (%)		
No	10 (20.8)	12 (25.0)
Yes	38 (79.2)	36 (75.0)
Accommodation; N (%)		
Independent	38 (79.2)	41 (85.4)
Supported	9 (18.8)	4 (8.3)
Homeless/roofless	0 (0.0)	1 (2.1)
Other	1 (2.1)	2 (4.2)
Main diagnosis (ICD-10 code); N (%)		
F10–F19	0 (0.0)	0 (0.0)
F20–F29	1 (2.3)	7 (15.9)
F30–F39	15 (34.9)	16 (36.4)
F40–F48	6 (14.0)	8 (18.2)
F50	0 (0.0)	0 (0.0)
F60–F69	7 (16.3)	8 (18.2)
F80–F89	0 (0.0)	0 (0.0)
F90–F98	0 (0.0)	0 (0.0)
F99	0 (0.0)	0 (0.0)
Other	14 (32.6)	5 (11.4)
Service type; N (%)		
Primary care	24 (50.0)	16 (33.3)
Secondary care	44 (91.7)	40 (83.3)
Social services	1 (2.1)	0 (0.0)
Other	1 (2.1)	1 (2.1)

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Appendix 5 Economic evaluation results tables and figures

TABLE 13 Mean resource use in quantities over the 12-month trial period by trial arm

	DIALOG+ (*N* = 189)		Active control (*N* = 176)	
	N[a]	Mean (SD) (minimum, maximum)	*N*[a]	Mean (SD) (minimum, maximum)
Inpatient stay				
General hospital stay (attendance)	114	0.09 (0.31) (0, 2)	99	0.07 (0.29) (0, 2)
Day service (attendance)	114	0.01 (0.09) (0, 1)	99	0 (0.00) (0, 0)
A&E service (attendance)	115	0.12 (0.52) (0, 4)	99	0.02 (0.14) (0, 1)
Psychiatry hospital stay (days)	113	0.52 (5.46) (0, 58)	102	1.18 (11.88) (0, 120)
Outpatient and community service (number of contact)				
General practitioner	114	6.39 (7.66) (0, 49)	98	5.33 (5.88) (0, 32)
Care co-ordinator	112	11.56 (12.16) (0, 51)	99	12.69 (13.00) (0, 64)
Psychiatrist	116	1.55 (2.08) (0, 9)	101	2.75 (3.83) (0, 22)
Other specialist doctor	116	1.72 (3.07) (0, 17)	100	1.39 (2.30) (0, 13)
Psychologist	115	4.68 (10.24) (0, 52)	100	4.14 (9.27) (0, 50)
Community psychiatric nurse	113	2.39 (8.48) (0, 80)	99	1.21 (3.94) (0, 30)
Social worker	115	0.46 (3.42) (0, 36)	101	0.91 (3.98) (0, 26)
Mental health nurse	114	0.93 (2.87) (0, 16)	101	0.62 (2.28) (0, 17)
Primary care nurse	114	2.09 (5.99) (0, 60)	101	2.09 (5.21) (0, 48)
Support worker	114	12.78 (39.39) (0, 252)	101	9.18 (38.02) (0, 360)
Drug and alcohol advisor	114	0.65 (3.78) (0, 26)	101	0.21 (1.48) (0, 14)
Other therapist or counsellor	115	3.41 (7.22) (0, 32)	100	2.84 (7.36) (0, 34)
Dentist	115	1.39 (1.80) (0, 7)	99	1.51 (1.90) (0, 8)
Other	110	1.78 (4.73) (0, 27)	96	2.76 (17.18) (0, 168)
Medication				
Total medication cost (£)	83	391.79 (1367.72) (0, 12,225)	75	209.31 (221.28) (0, 1054)
Family support and help (hours)				
Personal support	76	437.55 (578.20) (0, 2392)	66	434.12 (706.82) (0, 3302)
Child care	97	15.01 (109.01) (0, 1040)	89	32.43 (156.80) (0, 1040)
Help in/around the house	84	156 (316.95) (0, 1560)	78	182.67 (380.23) (0, 2158)
Help outside the home	86	77.7 (183.31) (0, 1092)	75	67.25 (104.88) (0, 468)
Other support	99	9.72 (66.92) (0, 650)	87	3.29 (16.73) (0, 130)

TABLE 13 Mean resource use in quantities over the 12-month trial period by trial arm (*continued*)

	DIALOG+ (*N* = 189)		Active control (*N* = 176)	
	N[a]	Mean (SD) (minimum, maximum)	*N*[a]	Mean (SD) (minimum, maximum)
Productivity lost				
Off sick from work (days)	113	4.35 (20.76) (0, 180)	100	9.72 (33.10) (0, 210)
Criminal justice services				
Police (minutes)	110	54.73 (343.94) (0, 3375)	100	16.1 (86.03) (0, 720)
Probation officer (minutes)	113	0 (0.00) (0, 0)	100	0 (0.00) (0, 0)
Court attendance (minutes)	113	8.5 (90.31) (0, 960)	100	0.15 (1.50) (0, 15)
Solicitor (minutes)	113	12.23 (94.24) (0, 960)	100	3.9 (30.65) (0, 300)
Police cell (nights)	141	0.02 (0.14) (0, 1)	125	0.02 (0.20) (0, 2)
Prison (nights)	132	0.01 (0.09) (0, 1)	118	0 (0.00) (0, 0)
Intervention training and session				
Length of training per clinician (minutes)	57	67.61 (25.25) (19, 141)	59	21.66 (14.84) (4, 71)
Length of a session per patient (minutes)	133	36.57 (25.42) (0, 115)	139	32.14 (29.37) (0, 130)
N of sessions attended per patient	133	3.57 (2.64) (1, 12)	139	5.91 (5.90) (1, 36)

A&E, accident and emergency.
a *N* refers to the number of participants who responded to each question.

TABLE 14 Mean costs for resource use over the 12-month trial period by trial arm

	DIALOG+ (*N* = 189)		Active control (*N* = 176)		Difference (no adjustment)[a]
	N[b]	Mean (SD)	*N*[b]	Mean (SD)	Difference (95% CI)
Inpatient service					
General hospital stay	114	231.75 (828.90)	99	186.81 (778.32)	44.95 (−176.94 to 266.83)
Day service	114	9.11 (97.22)	99	0 (0.00)	9.11 (−8.63 to 26.84)
A&E service	115	29.46 (124.75)	99	4.89 (34.22)	24.57* (1.51 to 47.64)
Psychiatry hospital stay	113	223.47 (2335.23)	102	503.53 (5085.40)	−280.06 (−1340.46 to 780.34)
Subtotal	113	485.12 (2458.38)	99	710.48 (5200.88)	−225.37 (−1323.83 to 873.09)
Outpatient and community service					
General practitioner	114	217.12 (260.41)	98	181.10 (199.92)	36.02 (−27.25 to 99.29)
Care co-ordinator	111	437.28 (501.66)	98	410.87 (480.67)	26.41 (−105.93 to 158.75)
Psychiatrist	115	105.84 (168.61)	101	194.64 (339.07)	−88.80* (−164.25 to −13.35)
Other specialist doctor	116	129.10 (271.94)	100	99.76 (188.86)	29.33 (−34.25 to 92.92)
Psychologist	115	256.79 (569.59)	99	227.37 (531.47)	29.42 (−112.34 to 171.18)
Community psychiatric nurse	113	71.98(318.45)	99	28.90 (87.59)	43.08 (−17.54 to 103.71)
Social worker	115	18.55 (142.86)	101	32.54 (175.42)	−14.00 (−58.02 to 30.03)
Mental health nurse	114	24.13 (79.55)	101	11.94 (42.79)	12.19 (−4.63 to 29.01)
Primary care nurse	113	24.46 (91.15)	99	26.93 (114.43)	−2.48 (−30.48 to 25.53)

continued

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TABLE 14 Mean costs for resource use over the 12-month trial period by trial arm (*continued*)

	DIALOG+ (*N* = 189)		Active control (*N* = 176)		Difference (no adjustment)[a]
	N[b]	Mean (SD)	*N*[b]	Mean (SD)	Difference (95% CI)
Support worker	113	289.18 (911.81)	101	201.73 (937.83)	87.45 (−149.53 to 324.42)
Drug and alcohol advisor	114	22.61 (133.90)	101	5.46 (36.27)	17.15 (−8.01 to 42.32)
Other therapist or counsellor	115	120.88 (257.89)	99	94.92 (264.54)	25.96 (−43.16 to 95.07)
Dentist	114	94.18 (154.20)	96	77.75 (127.74)	16.42 (−21.00 to 53.85)
Other	110	50.13 (158.30)	96	70.05 (446.11)	−19.91 (−112.10 to 72.28)
Subtotal	96	1833.88 (1818.35)	81	1706.70 (1695.51)	127.18 (−371.33 to 625.69)
DIALOG+/active control treatments					
DIALOG+ training	178	6.40 (3.94)	161	2.35 (2.05)	4.04* (3.38 to 4.70)
Provision of DIALOG+/active control	189	10.18 (7.51)	176	8.82 (8.61)	1.36 (−0.31 to 3.03)
Subtotal	178	16.86 (9.37)	161	12.00 (9.04)	4.86* (2.92 to 6.80)
Costs for medication	83	391.79 (1367.72)	75	209.31 (221.28)	182.48 (−111.52 to 476.47)
Other costs					
Costs for family support and help	65	14,958.80 (20,578.40)	56	14,955.11 (22,668.12)	3.69 (−7677.51 to 7684.89)
Costs for productivity lost	113	363.12 (1630.34)	100	737.46 (2440.33)	−374.34 (−924.90 to 176.21)
Costs for criminal justice services	109	22.35 (132.49)	98	5.55 (25.76)	16.80 (−8.93 to 42.54)
Total costs (NHS and PSS perspectives)	70	3028.54 (4011.27)	58	2729.54 (7042.93)	299.00 (−1734.35 to 2332.35)
Total costs (societal perspective)	40	15,071.60 (16,664.85)	31	19,363.57 (20,579.64)	−4291.97 (−13,196.24 to 4612.30)

* *p*-value is < 0.05.
A&E, accident and emergency.
a Independent *t*-tests are reported; 95% CI was produced using bootstrap method with 1000 replications.
b *N* refers to the number of participants who responded to each question.

TABLE 15 Comparison of EQ-5D-5L, MANSA and ICECAP-A data by trial arm

	DIALOG+ (*N* = 189)		Active control (*N* = 176)		Difference (no adjustment)[a]
	N[b]	Mean (SD) (minimum, maximum)	*N*[b]	Mean (SD) (minimum, maximum)	Difference (95% CI)
EQ-5D-5L					
Index at baseline	185	0.381 (0.300) (−0.353, 0.987)	175	0.41 (0.291) (−0.529, 0.987)	−0.029 (−0.089 to 0.031)
Index at 6 months	141	0.445 (0.324) (−0.383, 0.989)	124	0.453 (0.271) (−0.256, 0.989)	−0.008 (−0.080 to 0.064)
Index at 12 months	133	0.462 (0.329) (−0.292, 0.987)	119	0.47 (0.294) (−0.387, 0.987)	−0.007 (−0.085 to 0.070)
QALY over 6 months[c]	140	0.207 (0.142) (−0.128, 0.458)	124	0.218 (0.130) (−0.194, 0.427)	−0.011 (−0.044 to 0.021)
QALY over 12 months[c]	115	0.435 (0.294) (−0.289, 0.931)	101	0.451 (0.259) (−0.273, 0.888)	−0.016 (−0.090 to 0.058)

TABLE 15 Comparison of EQ-5D-5L, MANSA and ICECAP-A data by trial arm (*continued*)

	DIALOG+ (*N* = 189)		Active control (*N* = 176)		Difference (no adjustment)[a]
	N[b]	Mean (SD) (minimum, maximum)	*N*[b]	Mean (SD) (minimum, maximum)	Difference (95% CI)
MANSA					
At baseline	189	3.521 (0.708) (1.833, 4.833)	176	3.555 (0.800) (1.500, 5.250)	−0.034 (−0.188 to 0.121)
At 6 months	148	4.062 (0.930) (1.667, 6.500)	132	4.095 (0.811) (2.167, 5.833)	−0.033 (−0.235 to 0.169)
At 12 months	141	4.243 (0.899) (2.167, 6.583)	128	4.113 (1.023) (1.333, 5.917)	0.131 (−0.103 to 0.364)
ICECAP-A					
Index at baseline	185	0.476 (0.177) (0.077, 0.888)	172	0.486 (0.182) (0.119, 0.942)	−0.010 (−0.046 to 0.026)
Index at 6 months	141	0.540 (0.221) (−0.001, 1.000)	127	0.529 (0.207) (0.077, 1.000)	0.011 (−0.041 to 0.062)
Index at 12 months	131	0.581 (0.216) (0.119, 1.000)	119	0.561 (0.225) (−0.001, 1.000)	0.020 (−0.035 to 0.076)
YFC over 6 months[d]	139	0.257 (0.089) (0.038, 0.462)	125	0.259 (0.090) (0.068, 0.479)	−0.002 (−0.023 to 0.019)
YFC over 12 months[b]	111	0.546 (0.182) (0.094, 0.962)	101	0.539 (0.190) (0.107, 0.967)	0.007 (−0.043 to 0.058)

a Independent *t*-tests are reported; 95% CI was produced using bootstrap method with 1000 replications.
b *N* refers to the number of participants who responded to each question.
c QALY over 6 months = 0.25 X (index at baseline + index at 6 months). QALY over 12 months = 0.25 X (index at baseline + index at 12 months) + 0.5 X (index at 6 months).
d YFC over 6 months = 0.25 X (index at baseline + index at 6 months). YFC over 12 months = 0.25 X (index at baseline + index at 12 months) + 0.5 X (index at 6 months).

TABLE 16 Cost-effectiveness analysis

Analysis types	Cost differences (95% CI)	Outcome differences (95% CI)	ICER (£/QALY gained)	Probability of cost-effectiveness at £20,000/QALY	Probability of cost-effectiveness at £30,000/QALY
Base-case analysis (EQ-5D-5L at 12 months)[a]	114.45 (−598.39 to 768.31)	0.0241 (−0.0016 to 0.0478)	4749	79.8%	87.0%
Sensitivity analysis 1 (complete-case analysis)[b]	144.39 (−2904.75 to 3193.53)	0.0116 (−0.0694 to 0.0925)	12,447	75.6%	81.0%
Sensitivity analysis 2 (6-month time horizon)[a]	229.22 (−42.09 to 492.42)	0.0091 (−0.0000 to 0.0185)	25,189	39.5%	58.7%
Sensitivity analysis 3 (societal perspective)[a]	−620.61 (−3623.31 to 1987.38)	0.0262 (−0.0000 to 0.0504)	Dominant	N/A	N/A
Sensitivity analysis 4 (MANSA as outcome measure)[a]	220.31 (−477.41 to 875.84)	0.1891 (0.0508 to 0.3105)	N/A	N/A	N/A
Sensitivity analysis 5 (ICECAP-A as outcome measure)[a]	174.31 (−542.71 to 823.13)	0.0291 (−0.0038 to 0.0576)	N/A	N/A	N/A
Analysis types				Incremental net monetary benefit at £20,000/QALY (95% CI)	Incremental net monetary benefit at £30,000/QALY (95% CI)
Sensitivity analysis 6[c] (remote mode – with face-to-face mode as reference)				1632.01 (−5870.43 to 9134.46)	1153.57 (−5996.18 to 8303.31)

continued

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TABLE 16 Cost-effectiveness analysis (*continued*)

Analysis types	Cost differences (95% CI)	Outcome differences (95% CI)	ICER (£/QALY gained)	Probability of cost-effectiveness at £20,000/QALY	Probability of cost-effectiveness at £30,000/QALY
Sensitivity analysis 6[c] (mixed mode – with face-to-face mode as reference)				4488.06 (−3811.57 to 12,787.69)	3896.82 (−4334.67 to 12,128.30)

N/A, not applicable.

a Bivariate generalised linear mixed-effects model with baseline (costs and outcomes) and covariates (patients' age, gender, marital status, ethnicity, education attainment, employment status, site) controlled. A random effect of clinicians was included. 95% CI was produced using bootstrap replication for 1000 times.

b Mixed-effects model with baseline (costs and outcomes) and covariates (patients' age, gender, marital status, ethnicity, education attainment, employment status, site) controlled. A random effect of clinicians was included.

c The dependent variable is participant level of net monetary benefit (calculated by WTP threshold × 12-month QALY − 12-month total costs). Independent variables include delivery mode (i.e. face-to-face remote or mixed modes), treatment dummy (DIALOG+ or active control), interactions between delivery mode and treatment dummy, baseline costs and outcomes, and covariates (patients' age, gender, marital status, ethnicity, education attainment, employment status, site). Mixed-effects model was applied, with a random effect of clinicians included. The sample size is $N = 94$.

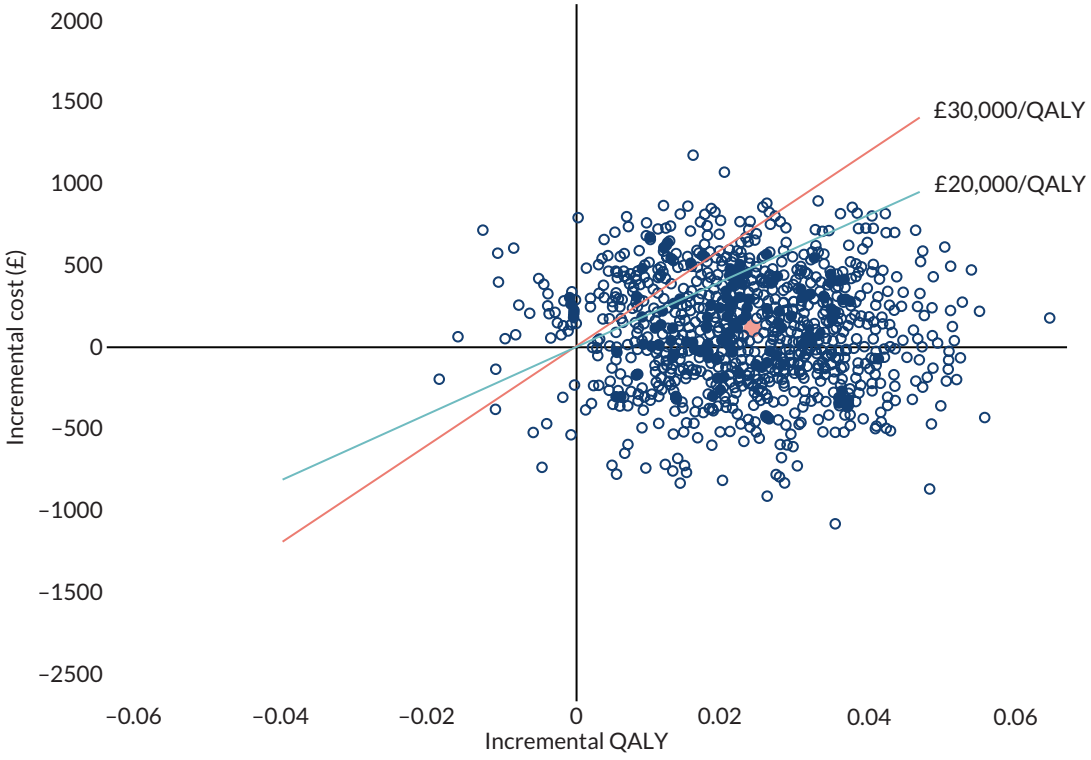

FIGURE 4 Cost-effectiveness plane.

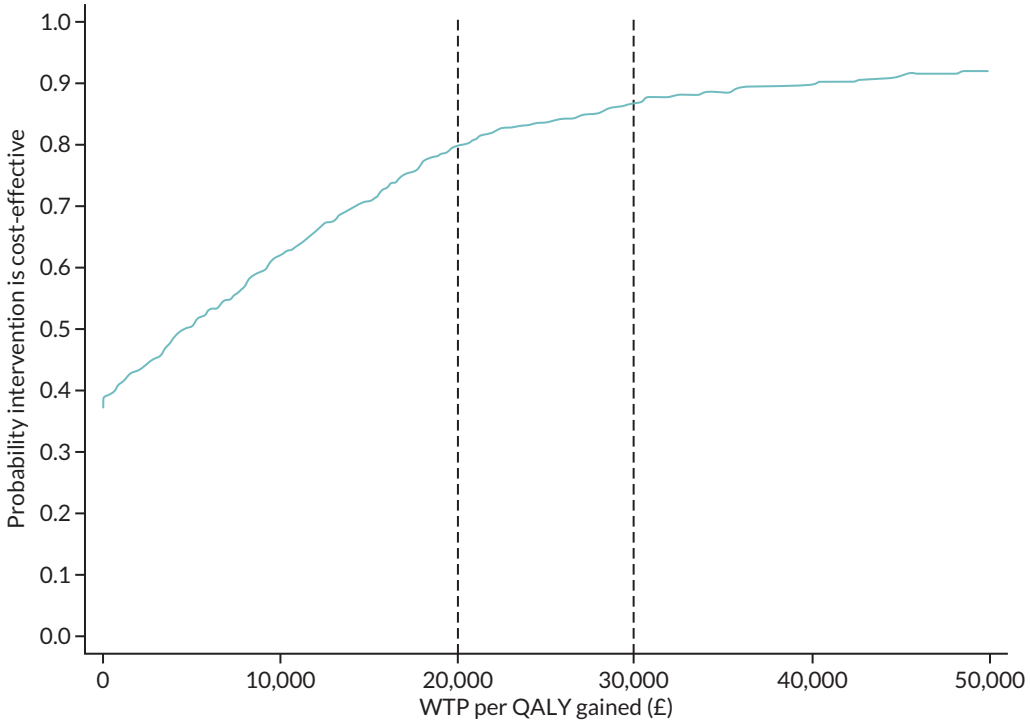

FIGURE 5 Cost-effectiveness acceptability curve.

TABLE 17 Mean costs for resource use over 6 months before baseline by trial arm

	DIALOG+ (*N* = 189)		Active control (*N* = 176)		Difference (no adjustment)[a]
	N[b]	Mean (SD)	*N*[b]	Mean (SD)	Difference (95% CI)
Inpatient service					
General hospital stay	185	242.78 (1056.76)	174	151.84 (678.96)	90.94 (−91.21 to 273.09)
Day service	185	5.61 (76.32)	174	0 (0.00)	5.61 (−5.22 to 16.44)
A&E service	185	7.85 (49.84)	174	11.13 (57.10)	−3.28 (−14.54 to 7.98)
Psychiatry hospital stay	185	837.49 (3651.34)	175	1012.53 (6732.54)	−175.03 (−1266.73 to 916.67)
Subtotal	184	1094.03 (3876.80)	174	1181.31 (6761.47)	−87.28 (−1203.93 to 1029.37)
Outpatient and community service					
General practitioner	182	126.29 (170.79)	169	114.27 (121.21)	12.01 (−18.74 to 42.76)
Care co-ordinator	183	313.65 (394.92)	170	327.36 (454.28)	−13.71 (−100.97 to 73.56)
Psychiatrist	184	68.01 (101.25)	172	107.71 (164.03)	−39.70* (−67.12 to −12.28)
Other specialist doctor	182	58.84 (130.40)	174	45.35 (168.53)	13.49 (−18.05 to 45.03)
Psychologist	184	83.50 (247.16)	174	94.75 (272.47)	−11.25 (−64.96 to 42.46)
Community psychiatric nurse	183	29.21 (133.76)	172	18.12 (72.19)	11.09 (−10.70 to 32.88)
Social worker	184	15.94 (109.97)	174	14.18 (72.40)	1.76 (−18.47 to 21.99)
Mental health nurse	182	26.89 (194.93)	175	18.20 (83.67)	8.68 (−20.46 to 37.83)
Primary care nurse	178	11.15 (36.24)	171	18.97 (111.53)	−7.81 (−25.14 to 9.51)

continued

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TABLE 17 Mean costs for resource use over 6 months before baseline by trial arm (*continued*)

	DIALOG+ (*N* = 189)		Active control (*N* = 176)		Difference (no adjustment)[a]
	N[b]	Mean (SD)	*N*[b]	Mean (SD)	Difference (95% CI)
Support worker	183	132.27 (530.25)	172	184.47 (657.02)	−52.20 (−177.02 to 72.61)
Drug and alcohol advisor	184	12.05 (98.29)	175	7.77 (60.54)	4.27 (−12.90 to 21.45)
Other therapist or counsellor	183	37.11 (141.16)	173	44.86 (176.70)	−7.76 (−40.54 to 25.02)
Dentist	182	30.62 (78.67)	174	39.15 (89.31)	−8.53 (−26.26 to 9.21)
Other	180	78.52 (410.07)	167	33.70 (125.69)	44.82 (−16.81 to 106.45)
Subtotal	161	1025.13 (1092.51)	146	1054.66 (1029.30)	−29.53 (−259.24 to 200.18)
Costs for medication	161	208.08 (668.86)	151	118.98 (190.07)	89.10 (−21.15 to 199.35)
Costs for family support and help	133	7838.71 (11,825.13)	128	7779.69 (11,472.90)	59.02 (−2691.52 to 2809.55)
Costs for productivity lost	185	240.01 (1517.40)	172	701.63 (2491.26)	−461.62* (−896.52 to −26.72)
Costs for criminal justice services	181	15.67 (108.29)	171	17.65 (128.15)	−1.98 (−26.45 to 22.48)
Total costs (NHS and PSS perspectives)	140	2491.48 (4669.27)	129	2019.88 (3828.30)	471.60 (−514.31 to 1457.50)
Total costs (societal perspective)	106	11,209.13 (14,222.56)	95	10,926.1 (12,711.86)	283.03 (−3408.15 to 3974.20)

* *p*-value is < 0.05.
A&E, accident and emergency.
a Independent *t*-tests are reported; 95% CI was produced using bootstrap method with 1000 replications.
b *N* refers to the number of participants who responded to each question.

TABLE 18 Mean costs for resource use over the 6-month trial period by trial arm

	DIALOG+ (*N* = 189)		Active control (*N* = 176)		Difference (no adjustment)[a]
	N[b]	Mean (SD)	*N*[b]	Mean (SD)	Difference (95% CI)
Inpatient service					
General hospital stay	139	114.04 (538.87)	125	84.54 (574.93)	29.50 (−102.89 to 161.89)
Day service	139	7.47 (88.04)	125	0 (0.00)	7.47 (−7.07 to 22.01)
A&E service	140	13.83 (63.41)	125	3.87 (30.49)	9.96 (−1.59 to 21.50)
Psychiatry hospital stay	138	9.30 (81.23)	126	118.89 (1334.52)	−109.58 (−343.35 to 124.18)
Subtotal	138	136.45 (545.42)	125	208.26 (1450.74)	−71.81 (−339.01 to 195.39)
Outpatient and community service					
General practitioner	140	106.13 (130.79)	126	85.54 (97.38)	20.59 (−7.62 to 48.80)
Care co-ordinator	139	257.79 (318.79)	124	253.81 (335.10)	3.97 (−74.13 to 82.08)
Psychiatrist	140	69.10 (140.55)	126	114.89 (188.87)	−45.79* (−87.09 to −4.49)
Other specialist doctor	141	58.40 (142.71)	125	41.84 (122.34)	16.56 (−15.53 to 48.65)
Psychologist	141	124.88 (312.21)	124	106.49 (312.58)	18.38 (−53.63 to 90.40)
Community psychiatric nurse	138	42.83 (198.02)	126	17.32 (70.04)	25.50 (−9.60 to 60.61)

TABLE 18 Mean costs for resource use over the 6-month trial period by trial arm (*continued*)

	DIALOG+ (*N* = 189)		Active control (*N* = 176)		Difference (no adjustment)[a]
	N[b]	Mean (SD)	*N*[b]	Mean (SD)	Difference (95% CI)
Social worker	139	9.93 (94.97)	126	15.56 (123.51)	−5.63 (−31.52 to 20.26)
Mental health nurse	139	13.48 (56.05)	126	11.19 (47.63)	2.29 (−10.40 to 14.99)
Primary care nurse	137	9.82 (24.01)	126	15.43 (70.09)	−5.61 (−18.61 to 7.40)
Support worker	137	86.01 (335.53)	125	108.53 (443.66)	−22.52 (−114.98 to 69.94)
Drug and alcohol advisor	138	15.19 (100.07)	126	1.42 (9.27)	13.76 (−2.98 to 30.51)
Other therapist or counsellor	138	59.73 (163.96)	124	52.12 (167.36)	7.61 (−33.95 to 49.17)
Dentist	136	36.94 (78.84)	123	42.67 (83.36)	−5.73 (−25.43 to 13.97)
Other	138	81.54 (633.43)	121	56.18 (405.61)	25.36 (−101.56 to 152.27)
Subtotal	125	1006.56 (1133.08)	112	957.51 (965.47)	49.05 (−205.03 to 303.14)
DIALOG+/active control treatments					
DIALOG+ training	178	6.4 (3.94)	161	2.35 (2.05)	4.04* (3.38 to 4.70)
Provision of DIALOG+/active control	189	10.18 (7.51)	176	8.82 (8.61)	1.36 (−0.31 to 3.03)
Subtotal	178	16.86 (9.37)	161	12.00 (9.04)	4.86* (2.92 to 6.80)
Costs for medication	115	204.27 (682.77)	101	115.92 (168.45)	88.35 (−41.73 to 218.43)
Costs for family support and help	104	7232.25 (11,368.38)	91	8572.57 (16,556.80)	−1340.32 (−5433.94 to 2753.29)
Costs for productivity lost	139	194.82 (980.72)	123	560.22 (1850.91)	−365.40 (−735.54 to 4.74)
Costs for criminal justice services	139	16.39 (117.39)	124	13.74 (75.86)	2.65 (−21.04 to 26.34)
Total costs (NHS and PSS perspectives)	100	1466.29 (1551.59)	87	1098.19 (981.75)	368.10* (2.75 to 733.44)
Total costs (societal perspective)	76	8588.67 (11,849.98)	62	10,436.99 (13,474.71)	−1848.32 (−6229.62 to 2532.98)

* *p*-value is < 0.05.
A&E, accident and emergency.
a Independent t-tests are reported; 95% CI was produced using bootstrap method with 1000 replications.
b *N* refers to the number of participants who responded to each question.

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Appendix 6 DIALOG experience questionnaire



CASE REPORT FORM v3.0, 21.Jun.2019

DIALOG+ EXPERIENCE QUESTIONNAIRE

Assessment Date (DD•MMM•YYYY) ☐☐•☐☐☐•☐☐☐☐ **Participant ID** ☐☐☐☐☐ **Researcher ID** ☐☐☐

6- MONTH ASSESSMENT ☐ **12- MONTH ASSESSMENT** ☐

Chief Investigator: Dr Victoria Bird
IRAS ID: 263211

TACK					
Participant ID	☐☐☐☐☐	Researcher ID	☐☐☐		T A C K TACKLING CHRONIC DEPRESSION

1. DIALOG+ Experience Questionnaire

(to be completed by an unblinded researcher)

Please answer the following questions regarding your experience of DIALOG+ over the past 6 months. Please use the response options provided and write the number which is most relevant to you in the box.

1. How useful did you find using DIALOG+?

0	1	2	3	4	
Totally useless	A little useless	In the middle	A little useful	Very useful	☐

2. How easy did you find it to use the DIALOG+ intervention?

0	1	2	3	4	
Very difficult	A little difficult	Neither easy nor difficult	A little easy	Very easy	☐

3. How satisfied were you with your treatment whilst using DIALOG+?

0	1	2	3	4	
Totally dissatisfied	A little dissatisfied	Neither satisfied or dissatisfied	A little satisfied	Totally satisfied	☐

4. How much did you like going through the process of DIALOG+ *(including completing the DIALOG scale and the 4 step approach)* **?**

0	1	2	3	4	
Totally dissatisfied	A little dissatisfied	Neither satisfied or dissatisfied	A little satisfied	Totally satisfied	☐

5. Did receiving DIALOG+ affect the relationship with your clinician?

0	1	2	3	4	
Impacted relationship in a very negative way	Impacted relationship a little in a negative way	Had no impact on relationship	Impacted relationship a little in a positive way	Impacted relationship in a positive way	☐

6. How easy was it to use the tablet device during the sessions?

0	1	2	3	4	
Very difficult	A little difficult	Neither easy nor difficult	A little easy	Very easy	☐

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TACK

Participant ID	☐☐☐☐☐	Researcher ID	☐☐☐	

TACK — TACKLING CHRONIC DEPRESSION

7. Did you prefer DIALOG+ to the treatment you have received previously? ☐

0	1	2	3	4
Preferred previous treatment a great deal	Preferred previous treatment a little	Have no preference	Prefer DIALOG+ a little	Prefer DIALOG+ a great deal

☐ **please tick this box if you have never previously received treatment for depression**

Below is space for you to add any additional comments about your experience of using DIALOG+. If there is anything important about your experience of receiving DIALOG+ that has not been covered by the above questions then please write it down here:

_____

_____

_____

_____

_____

Once all items on the CRF have been answered, please sign and date below confirming that the data is accurate and complete.

Researcher ID

☐☐☐

Signature:_____

Date: ☐☐•☐☐☐•☐☐☐☐

d d m m m y y y y

Appendix 7 Work package 5 process evaluation sampling strategy

Recruitment of service users

Around 36 purposively selected service users (≈ 6 from each trial site), who were allocated to the intervention arm, were planned to be assessed as part of the process evaluation. They were invited to take part in individual qualitative (semistructured) interviews.

Each interview was conducted after the 12-month follow-up assessment so that the interviews did not interfere with the effects of the intervention in influencing the primary outcome (SQoL at 12 months). Consequently, unblinded researchers only identified suitable participants and conducted the interviews.

Sampling of service users

Service users were purposively sampled based on a number of criteria: (1) the level of engagement with the DIALOG+ intervention as indicated by the number of DIALOG+ sessions received; (2) whether the DIALOG+ intervention was successful in improving QoL or not, as measured by the difference in MANSA scale score at baseline versus 6-month follow-up; and (3) the level of satisfaction with the DIALOG+ intervention as measured by the DIALOG+ experience scale at 6 months. Additionally, participant characteristics, such as (4) age, (5) gender and (6) study site, were used to ensure a varied sample. We will also took into account whether service users were newly referred to the service at the start of intervention delivery or had an established relationship with their clinicians.

The criteria listed above were identified in the following ways by local researchers: (1) health economic data (from the Inventory Forms) were used to identify the number of completed DIALOG+ sessions for each participant; (2) the difference in MANSA score between baseline and 6-month follow-up was used to identify individuals with positive and negative changes in the SQoL; and (3) the score on the DIALOG+ experience scale (question 3) at 6 months was used to establish the level of the participant's satisfaction with DIALOG+ treatment.

The sampling framework is presented in *Table 19*. The figures presented in 'per site' column are minimum figures required for each of the sampling criteria to make sure that the service users with these characteristics are represented in the total sample. We will monitor and guide recruitment in each site in order to achieve the total number participant service users required for each sampling criterion for the whole study.

Topic guide for service users

The topic guide for the semistructured interviews was developed with input from the LEAP. The questions investigate both the benefits and the downsides of receiving the DIALOG+ intervention. The participating service users were about the helpfulness of DIALOG+ overall and its specific elements in managing their mental health and other aspects of life; the impact on their relationship with the treating clinician, barriers and difficulties encountered; and suggestions for improvements and acceptability for future use. We also explored the participants' experiences of receiving DIALOG+ during the COVID-19 pandemic and took into account whether they received the intervention face-to-face, remotely (over the phone), virtually (via online platforms) or as a combination of different modes of delivery.

Service users were paid £15 as a reimbursement for their time.

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TABLE 19 Sampling framework for service-user participants

Sampling criteria
Primary criteria
DIALOG+ completion[a]
High completion: ≥ 4 sessions received
Average: 3 sessions received
Low completion: ≤ 2 sessions received
SQoL improvement[b]
Improvement in SQoL score
No change
Reduction in SQoL score
D+ treatment satisfaction[c]
Satisfied: D+ Exp Q3 Score ≥ 3
Neither: D+ Exp Q3 Score = 2
Dissatisfied: D+ Exp Q3 Score ≤ 2
Gender
Female
Male
Age (years)
18–40
40–65
65+
Secondary criteria
Patient status
New referrals
Existing patients

a Special attention will be paid to service users who stopped attending sessions or withdrew their consent for the intervention mid-way through delivery.
b The SQoL improvement is defined as any improvement in MANSA score between baseline and 6 months.
c Treatment satisfaction established on the basis of the response to Question 3 of DIALOG+ Experience Questionnaire.

Recruitment of mental health professionals

Around 24 mental health professionals who were allocated to the intervention arm were planned to be interviewed as part of the process evaluation. They were invited to take part in individual semistructured interviews.

Interviews with the selected clinicians were conducted after all patients in their cluster had completed the 12-month follow-up assessments. Both blinded and unblinded researchers were able to identify and interview the TACK clinicians, as blinding was lifted at this point. In case of the TACK clinician discharging all the patients from their cluster before 12-month follow-ups, such clinicians were interviewed earlier **by unblinded researchers only** to preserve the blinding of other researchers.

Sampling of mental health professionals

Mental health professionals were purposively sampled based on (1) how successfully they implemented DIALOG+ as indicated by the number of successfully delivered DIALOG+ sessions; (2) professional background; (3) clinical setting; (4) gender and (5) study site. The sampling framework is presented in *Table 20*.

Health economics data were used to establish the number of completed DIALOG+ sessions for the participating clinicians and identify those with high and low delivery rates. Sociodemographic data collected at baseline were be used to identify professional background of the clinicians.

TABLE 20 Sampling framework for clinician participants

Sampling criteria
Primary criteria
DIALOG+ completion
High completion: ≥ 10 sessions per cluster delivered
Medium completion: 4–10 sessions
Low completion: ≤ 4 sessions per cluster delivered
Professional background
Mental health nurses
Psychiatrists
Social workers
Primary care nurses
Support workers
Occupational therapist
Gender
Female
Male
Clinical setting
CMHTs
Primary/intermediary care
Secondary criteria
Length of experience in MH
Highly experienced: ≥ 11 years
Medium experience: 3–10 years
New to MH ≤ 2 years

MH, mental health.

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Topic guide for mental health professionals

The topic guide for the semistructured interviews was developed with input from clinicians in the TACK study group. The questions investigated both the benefits and the downsides encountered with DIALOG+. Clinicians were also asked about the helpfulness of the DIALOG+ overall and its specific elements; the impact on their relationship with the service users, barriers and difficulties encountered; compatibility with their usual style of working; possible differences in delivering the DIALOG+ to newly referred versus existing patients; suggestions for improvements and implementation within NHS; and acceptability for future use. We took into account different modes of delivery that the clinicians may have used: face-to-face, remote (over the phone) and/or virtual (via online platforms). The clinicians were also asked about their experiences of delivering DIALOG+ during the pandemic.

Appendix 8 Thematic analysis

Clinician themes		Service user themes	
Theme 1: Structured format for conversations		**1: Structure and focus**	
1.1	**Structured conversations**	**1.1**	**Structured conversations**
1.2	**Focused conversations**	*1.1.1*	*Importance of free-flowing conversations*
1.2.1	*Breaking issues down*	**1.2**	**Focused conversations**
1.3	**Mechanism for initiating new and in-depth conversations**	**1.3**	**Too prescriptive format**
1.4	**Restrictive and repetitive conversations**	*1.3.1*	*Restrictive and repetitive conversations*
1.4.1	*Hindering conversation flow*	*1.3.2*	*Painful conversations*
1.4.2	*Preventing follow-up conversations*	*1.3.3*	*Time-consuming format*
1.4.3	*Difficulties in keeping service users focused*		
1.5	**Mixed feelings about the impact of the format**		
Theme 2: Getting a bigger picture		**Theme 2: Getting a bigger picture**	
2.1	**Promoting a holistic approach**	**2.1**	**Holistic approach is helpful**
2.1.1	*Learning more about service users*	*2.1.1*	*Highlighting connections between mental health and other areas of life*
2.1.2	*Highlighting connections between mental health and other areas of life*	*2.1.2*	*Facilitating deeper exploration*
2.1.3	*Introducing new topics*	*2.1.3*	*Introducing new topics*
2.2	**Creating new ways of supporting service users**	**2.2**	**Holistic approach aids 'opening up'**
2.3	**Introducing areas that clinicians may find difficult to address**	**2.3**	**Creating awareness of how others can help**
Theme 3: Monitoring change		**Theme 3: Mapping the recovery journey**	
3.1	**Mapping patterns of change**	**3.1**	**DIALOG+ as a reflective tool**
3.11	*Identifying triggers*	**3.2**	**Identifying and prioritising issues of most importance to service users**
3.12	*Evidencing change*	**3.3**	**Tracking change**
3.13	*Tracking change provides directions for treatment*	*3.3.1*	*Identifying triggers*
3.14	*Satisfaction ratings reflect fluctuating moods*	*3.3.2*	*Evidence of change*
3.2	**Change talk**	*3.3.3*	*Visual display aids comprehension*
3.3	**Satisfaction ratings can be unreliable**	*3.3.4*	*'Going in the right direction'*
3.3.1	*Mismatch between satisfaction ratings and service user' feelings*	**3.4**	**Satisfaction ratings can be unreliable tools**
3.3.2	*Mismatch between clinician's and service user's views of satisfaction ratings*	*3.4.1*	*Discrepancies between satisfaction scores and actual feelings*
3.3.3	*Being rated by service users can be awkward*	*3.4.2*	*Difficulties of measuring complex feelings and circumstances*
3.4	**Challenges with obtaining satisfaction scores**	**3.5**	**Coming up with satisfaction ratings requires effort**
Theme 4: Focusing on strengths		**Theme 4: Focusing on strengths**	
4.1	**Shifting focus from problems**	**4.1**	**Highlighting areas of strength**

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Clinician themes		Service user themes	
4.2	**Exploring how to move forward**	*4.1.1*	*Satisfaction rating highlights areas of strength*
4.3	**Highlighting improvement**	*4.1.2*	*Exploring what works highlights areas of strength*
4.4	**The challenges of focusing on strengths**	*4.1.3*	*Positive feedback highlights areas of strength*
4.4.1	*Difficulties in adopting other perspectives*	*4.1.4*	*Awareness of improvement boosts confidence*
4.4.2	*Ratings can highlight lack of improvement*	**4.2**	**Introducing more hopeful perspectives**
4.4.3	*Being strengths based in a problem focused system*	*4.2.1*	*Retraining the mind*
		4.3	**The challenges of focusing on strengths**
		4.3.1	*Highlighting negatives*
		4.3.2	*Focus on strengths can invalidate feelings*
Theme 5: Working on solutions		**Theme 5: Working on solutions**	
5.1	**Benefits of solution-focused approach**	**5.1**	**Coming up with a plan**
5.1.1	*Encouraging service users to take an active role*	**5.2**	**Focusing on goals facilitates continuity of treatment**
5.1.2	*Manageable steps*	**5.3**	**Overcoming helplessness**
5.1.3	*Benefits of considering help of others*	**5.4**	**Collaborating with clinicians boosts motivation**
5.2	**Limitations of solution focused approach**	**5.5**	**Completing goals boosts confidence**
5.4.1	*Difficulties in engaging service users to come up with solutions*	**5.6**	**Limitations of goal setting**
5.4.2	*Completing goals can be difficult for service users*	*5.6.1*	*Lack of motivation*
5.4.3	*Difficulties with resistance to goal setting*	*5.6.2*	*Managing expectations*
		5.6.3	*Feeling under pressure to complete goals*
		5.6.4	*Preference for loosely defined goals*
Theme 6: The impact on therapeutic relationship		**Theme 6: The impact on therapeutic relationship**	
6.1	**Encouraging increased service user contribution**	**6.1**	**Enabling patient-centred treatment**
6.2	**Facilitating collaboration**	**6.2**	**Improving rapport**
6.3	**Developing trust**	*6.2.1*	*Holistic approach makes treatment more personal*
6.4	**Shifting responsibility to service users can be difficult**	*6.2.2*	*Building a friendly and trusting relationship*
6.3	**Impersonal conversations**	**6.3**	**DIALOG+ can make interactions feel impersonal**
		6.4	**Feeling unsupported**
		6.5	**The impact of technology**
		6.5.1	*Tablet facilitates trust and accountability*
		6.5.2	*Lack of human touch*
		6.5.3	*Incorrect use of technology can create a negative impact*
		Theme 7: The impact of technology	
		7.1	**DIALOG+ app as a visual aid**
		7.2	**Sharing a tablet facilitates patient involvement**
		7.3	**Difficulties with the app login and navigation**
		7.4	**Lack of integration with electronic medical records**
		7.5	**Using a tablet may negatively impact rapport**

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