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DIALOG+ for service users with chronic depression: a cluster-randomised controlled feasibility trial and qualitative evaluation

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Abstract

Background Many individuals who experience depression go on to develop chronic forms of this disorder yet research on tailored treatments is lacking. DIALOG+, a technology-assisted and resource-oriented intervention, may be one potential solution. This study aimed to assess the feasibility and acceptability of conducting a definitive cluster randomized controlled trial (cRCT) of DIALOG+ for service users with chronic depression.

Methods A mixed-methods feasibility study involving a two-arm cRCT and qualitative evaluation was conducted in community-based mental health care services in South-East England. Service users with a clinical diagnosis of chronic depression (≥ 2 years), and their clinicians, were cluster-randomized to either the intervention (DIALOG+) or an active control (Treatment as Usual + completion of the DIALOG scale) group. Participants were assessed at baseline and 6 months post-randomisation by blinded assessors. The DIALOG+ arm participants were interviewed about their experiences. The feasibility of recruitment and retention strategies, eligibility criteria, and selected outcome measures including their estimated variability were all assessed. Acceptability of DIALOG+ and fidelity evaluation recording methods were also explored.

Results Thirty-six service users and 11 clinicians were cluster-randomised to the intervention arm ($n = 25/8$) or the active control arm ($n = 11/3$). 75% of the target service user sample and 92% of the clinician sample were recruited. The service user retention rate was 77.8%. Recruitment was affected by organisational-level difficulties, however, all consented and eligible service users were randomised. Eligibility criteria for the subsequent main trial were modified to ensure adequate inclusiveness. The outcome measures used were feasible except for the clinician-rated ones which required replacement. No formal between-group tests were conducted however the results indicated a trend towards increased subjective quality of life (SQOL) and a decrease in depressive symptoms at 6-months in the DIALOG+ arm. Qualitative interviews were conducted with 7 service users and 6 clinicians, with data indicating that DIALOG+ is acceptable due to the intervention providing increased clarity and focus, and positively impacting on clinical communication. 85.7% of service users indicated they would want to use DIALOG+ again in the future.

Conclusions A definitive cRCT is feasible to conduct with some adjustments to the recruitment procedures and materials, eligibility criteria and clinician-rated outcome measures. DIALOG+ has a potential to increase SQOL and reduce depressive symptoms for service users with chronic depression.

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Keywords Chronic depression, Subjective quality of life, DIALOG+, Technology supported intervention, Feasibility study, Cluster randomised controlled trial, Mixed-methods, Mental health, Brief solution focused approach

Background

Depression is one of the most common mental disorders and is a leading cause of disability worldwide [1]. There is a widespread recognition of the burden it imposes not only to affected individuals, but also on health care systems and wider society. Despite the advances in and improved availability of treatments over the last few decades, there has been no decrease in depression prevalence in the general population [2, 3]. Service users with depression tend to be high utilisers of healthcare services while indirect costs due to absenteeism and lost employment can be even greater [4, 5].

A substantial proportion of people who experience an acute episode of depression go on to develop a chronic disorder, with many recurrences and/or long illness periods throughout their lives [3]. It has been estimated that 20–30% of individuals diagnosed with major depressive disorder, and up to 47% of those treated in mental health care services, suffer from chronic-recurrent forms [6]. Chronic depressive disorders are associated with poor clinical and social outcomes including more severe episodes, an increased suicide risk, physical comorbidity, reduced social networks and significant functional impairment [6–9]. Their adverse impact on quality of life, service use and economic costs is even more pronounced because they tend to start earlier in life [10–12]. Service users who suffer from chronic forms of depression are often difficult to treat [13, 14]. The available evidence rarely distinguishes between the incident (i.e. first onset) and chronic-recurrent cases with a resulting lack of understanding if the existing treatments are as effective for, and available to individuals with longer term depression [3]. Additionally, psychotherapy treatments are often expensive and require referrals to specialist services or professionals [15]. There is a need to develop evidence-based interventions that can be implemented across different clinical settings to make routine care for people with chronic depression more effective and accessible.

DIALOG+, a technology-assisted and resource-oriented intervention, might be one potential solution. The intervention is based on the principles of quality-of-life research, patient-centred communication, IT developments and solution-focused therapy [16]. 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 by facilitating more structured, patient-centred and solution-focused communication between service users and their clinicians in routine meetings. DIALOG+ was found to be effective for service users with psychosis in a previous randomised controlled trial, resulting in better subjective quality of life, fewer unmet needs, lower general symptom levels, better social outcomes, and lower treatment costs over a period of one year [17]. Research has shown that individuals who suffer from chronic depression have even lower quality of life compared to those with schizophrenia [18], however, they tend to have better resources such as more social contacts which can be mobilised in recovery [19]. A holistic, resource-oriented intervention targeting different aspects of life and not just mental health could potentially be even more effective for this service user group.

This feasibility study is part of the TACK programme of research (RP-PG-0615–200010), a 6-year project aiming to establish the acceptability, clinical- and cost-effectiveness of DIALOG+ for service users with chronic depression. The purpose of this study was to investigate the appropriateness of trial procedures before a definitive cluster randomised controlled trial (cRCT) and the acceptability of adapted DIALOG+ for this population. The key study objectives were to assess:

1. feasibility of recruitment and retention strategies for the definitive cRCT
2. feasibility of eligibility criteria
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, setting and participants

The study utilised a mixed-methods design involving a multicentre, two-arm cRCT and a qualitative evaluation. Each trial cluster consisted of an individual clinician and the participating service users from their caseload. The clusters were randomly allocated, in a 2:1 ratio, to either the intervention (DIALOG+) or to an active control (Treatment As Usual (TAU) + completion of the DIALOG scale with no input from the clinician) group. Outcome measures were administered at baseline and 6 months post-randomisation to assess a range of health, social and cost-related outcomes. Individual qualitative interviews were to be conducted at 6 months with all clinicians and a subset of service users allocated to the DIALOG+ trial arm to explore their experiences of delivering and receiving the intervention. The service user subsample was designed to be purposive based on their gender,

age, and experiences of receiving DIALOG + treatment, as indicated by their responses on the DIALOG + Experience Questionnaire completed at 6 months.

Service users and clinicians were recruited from six community-based services in three NHS England mental health Trusts: East London NHS Foundation Trust (ELFT); Barnet, Enfield and Haringey Mental Health Trust (BEH); and Essex Partnership University NHS Foundation Trust (EPUT). The participating services included four Community Mental Health Treatment teams, one Enhanced Primary Care team, and one Assessment and Brief Treatment team. The study recruitment and data collection were conducted between April 2018 and March 2020.

DIALOG + intervention

DIALOG + is a technology-assisted intervention available as an app and delivered on a tablet computer within routine meetings in mental health care settings. It draws upon the principles of solution-focused therapy to structure communication between clinicians and service users with the aim of developing more co-produced, holistic, and personalised care plans, and improving treatment outcomes. The presence of the tablet allows service users to be more actively involved in the meeting, providing a shared visual reference point, with the device intended to be easily passed between them and their clinicians.

Each session starts with a completion of the DIALOG scale, an 11-item quality of life (QoL) measure, which prompts service users to rate their satisfaction with eight life areas (mental health, physical health, job situation, accommodation, leisure activities, friendships, relationship with family/partner, personal safety) and three treatment aspects (medication, practical help, meetings with professionals). Each item is rated from 1 ("totally dissatisfied") to 7 ("totally satisfied"), followed by a question whether the service user wants additional help with that area. The ratings are summarised on screen, allowing for visual comparisons with those from previous sessions. Clinicians are instructed to discuss the satisfaction ratings with service users and offer positive feedback on any high-scoring or improving areas.

Following the collaborative review of the satisfaction ratings, service users are invited to select up to three areas for further in-depth discussion. Conversations about selected areas are structured according to a four-step approach informed by the principles of brief solution-focused therapy, with short guidance on each step available within the app. The aim is to encourage service users to identify their existing internal and external resources as well as strategies that could potentially be used to address any issues raised in the session. After reflecting on different options, service users are invited by clinicians to agree on concrete, achievable actions to be completed by themselves, clinicians and other people before the next session. There is a particular emphasis on identifying what service users can do themselves. The agreed actions are then recorded in the app, summarised by the clinician at the end of the current session, and reviewed at the beginning of the next one. The purpose of this approach is to collaboratively create more comprehensive and personalised treatment plans encompassing different areas of service users' life. A detailed description of the DIALOG + intervention is available in Priebe et al. [16].

The DIALOG+ intervention was purposefully developed as a generic and flexible tool to be used by a wide variety of mental health professionals in different care settings. The intervention structures communication within existing regular one-to-one appointments and does not require any additional sessions. Service users continue to receive any other treatment as usual including medication and psychological therapies. The delivery of the intervention can be adapted to the needs of individual clinicians and service users including personal therapeutic style and more practical considerations such as the number and frequency of sessions. The protocol for intervention delivery as part of this feasibility trial is described in the cRCT Trial Arms section.

The DIALOG+ manual and training were designed to be brief and accessible to a wide variety of professionals. Training sessions consist of delivering a brief presentation on the theoretical background and the development of the intervention; demonstrating how to use the intervention app; and instructing clinicians on how to deliver the solution-focused four-step approach. This is followed by showing training videos of DIALOG+ sessions, and a period of skills practice for clinicians. The sessions last up to 2 h and are delivered in either a one-to-one or group format, in-person or online. The DIALOG + manual, informational videos and other resources provided to the clinicians are available online at https://www.elft.nhs.uk/dialog/resources.

A summary of the DIALOG+ intervention is presented in Table 1 based on the TIDIeR checklist headings [20].

cRCT trial arms

The feasibility trial had two arms:

Intervention arm (DIALOG +)

The clinicians randomly allocated to the intervention arm delivered DIALOG + during routine in-person meetings with participating service users at least once per month, for a period of six months. This was based on the likely frequency established during the earlier, exploratory testing of the intervention. Their professional backgrounds are described in the Results section. The clinicians received the DIALOG + training as described in the

Table 1 DIALOG + intervention summary

Brief Name	DIALOG +
Why	DIALOG + is intended to provide structure to routine clinical interactions in order to improve patient reported outcomes and the experience of care
What	A technology-assisted and resource-oriented intervention based on the principles of quality-of-life research, patient-centred communication, IT developments and solution-focused therapy. The intervention is available as an app that can downloaded on computer tablets and other electronic devices
Materials	The participating clinicians were provided with computer tablets to access the DIALOG + app and deliver the intervention. The tablet was shared with service users during the DIALOG + sessions. The clinicians received the training consisting of a presentation on the development of the intervention, a demonstration of how to use the intervention app and deliver the solution-focused four-step approach, a period of observing training videos of DIALOG + sessions, and a period of skills practice. They were also provided with a DIALOG + manual. The information about the DIALOG app with download links, the training materials including the videos of DIALOG + sessions, and the DIALOG + manual are available online at https://www.elft.nhs.uk/dialog/resources
Procedures	Each DIALOG + session starts with a completion of the DIALOG scale, an 11-item quality of life (QoL) measure, which prompts service users to rate their satisfaction (1–7) with eight areas of their life and three aspects of care they have been receiving. The ratings are summarised on screen, allowing for visual comparisons between sessions, with clinicians instructed to discuss them with service users and offer positive feedback on any high-scoring or improving areas. This is followed by service users selecting up to three areas for further discussion. Conversations about selected areas are structured according to a four-step approach informed by the principles of brief solution-focused therapy, with short guidance on each step available within the app. Service users are encouraged to identify their existing internal and external resources and strategies they could use to address any issues raised in the session, discuss the options available to them, and decide on concrete, achievable actions to be completed by themselves, clinicians and other people until the next session. The agreed actions are recorded in the app, summarised by the clinician at the end of the session, and reviewed at the beginning of the next one. More information on the steps of the intervention is available online at https://www.elft.nhs.uk/dialog/resources
Who Provided	DIALOG + is a generic and flexible intervention that can be used by a wide variety of mental health professionals in different care settings. In this study, the intervention was delivered by psychiatric nurses, social workers, psychiatrists and mental health workers whose characteristics are available in Table 3
How	The intervention was delivered face-to-face during routine individual meetings with participating service users
Where	The intervention was delivered at the premises of community-based mental health services
When and How Much	For the purposes of this study the participating clinicians and service users agreed to deliver & receive the intervention at least once per month, for a period of six months, during already occurring routine appointments
Tailoring	DIALOG + was designed to be a flexible intervention that can be delivered in routine care, with frequency and length of sessions adapted to the needs of individual service users and their clinicians. No specifically prescribed tailoring was planned for this study
Modifications	The intervention was not modified during the course of this study
How well	The intervention adherence or fidelity was not assessed. At this was a feasibility trial, we only assessed acceptability of recording methods to be used for evaluating fidelity in the main RCT

previous section, delivered by members of the trial team. Training was delivered in either individual or group in-person sessions depending on the timing of recruitment and the availability of clinicians.

Active control arm (TAU + DIALOG scale)

To control for the novelty effect of using a tablet within routine meetings, and for repeated QOL assessments, an active control group was used as a comparator. Clinicians in this arm continued delivering treatment as usual in their routine meetings. In addition to this, at the end of each meeting, they asked participating service users to rate their satisfaction with 11 areas of life and treatment using the DIALOG scale on a provided tablet. Participants completed the ratings without any input from the clinicians and did not receive the solution-focused component of the intervention (the settings on the app were modified to only allow access to the DIALOG scale). Active control sessions were delivered at the same frequency as DIALOG + sessions, at least once per month for six months. The clinicians received a shorter 15-min training session to introduce them to the (modified) DIALOG app and explain how to rate the DIALOG scale.

Assessing feasibility of recruitment and retention strategies

To assess feasibility of the strategies to recruit service users from the target population and clinicians who treat them in the community-based mental health services, we recorded the number of participants identified, consented, screened for eligibility, and randomised to cRCT in both groups. To establish the retention rate for the participating service users the number of assessments at baseline and follow-up were recorded, as well as reasons for any dropouts. The recruitment and retention rates were monitored on a monthly basis through communication with local researchers, clinicians and the trial

statisticians. The issues encountered during recruitment and data collection were also regularly discussed with the members of the TACK Programme Steering Committee to develop plans on how to address them in the main cRCT design.

As the aim was to explore the feasibility of the trial procedures and to modify them accordingly where needed, and the target sample size was based on the broad estimation, we did not specify formal recruitment expectations. However, the trial team established expected recruitment percentage ranges prior to the trial, with a recruitment rate (for both clinician and service user samples) of > 80% regarded as "good" and a recruitment rate of between 50 and 80% being regarded as "acceptable" for the feasibility trial if the reasons for low recruitment were clearly identified and the strategies to address them in the definitive cRCT could be developed and agreed. In regard to the retention rate for the participating service users, a 6-month follow up completion rate of 80% or above for at least the primary outcome was classified as "good". A retention rate between 70 and 80% was deemed "acceptable" due to the well-known difficulties in recruiting service users with depression [21] and the pragmatic nature of this trial conducted in routine mental health services.

Sample size estimation

A formal sample size calculation was not conducted as the feasibility cRCT was not designed to detect a statistically significant difference [22]. Instead, we used a broad estimate for an adequate sample size based on the suggested range between 24 and 50 [23–25]. We planned to recruit 48 service users and 12 clinicians and randomise them on a 2:1 basis to ensure at least 30 individuals were allocated to the intervention arm [26]. Unequal randomisation, with more participants in the intervention arm, was primarily intended to test the feasibility of intervention delivery across sites, and is common practice in pilot trials where it is of more value to have a higher proportion of the sample receiving the treatment compared to a well-known standard of care [27].

Recruitment procedures

Researchers identified and recruited clinicians via weekly multidisciplinary meetings in the participating services. Caseloads were screened for potentially eligible service users by either clinicians themselves or researchers (if part of the clinical team), who would then contact them. Potential participants interested in the study were invited to face-to-face assessments with researchers who would then provide detailed information, answer any questions, and obtain written informed consent. At this point eligibility screening was also completed, with only individuals with SQoL scores < 5 on the MANSA, and with depressive symptoms ≥ 10 on the MADRS, proceeding to complete the remainder of the baseline assessment (see Table 2 for full eligibility criteria).

Randomisation and concealed allocation

We aimed to have an average cluster size of 4. As soon as this target was reached within a cluster, the clinician was randomised to either the intervention or the active control arm. If a clinician had less than 4 potential participants on their caseload, randomisation was carried out as soon as all eligible and willing service users were recruited. The randomisation was performed on a 2:1 ratio and was stratified by site and in blocks of 3 to ensure adequate distribution. The procedure was conducted by an independent statistician from the Pragmatic Clinical Trials Unit (PCTU) at Queen Mary University of London, using a computer-generated randomisation scheme. The allocation status of clinicians was known to the trial manager and senior members of the research team who informed them which arm they were randomised to, whilst outcome assessors and the trial statistician were blinded. Due to the nature of the intervention, it was not possible to conceal the allocation from participants.

Quantitative assessment procedures

Quantitative assessments with service users were completed at baseline and 6 months post-randomisation. The assessments were planned to be conducted face-to-face at either the participants' homes or NHS premises, depending on preference and/or any clinical considerations. Service users received financial reimbursement (£20) for each assessment.

Assessing feasibility of eligibility criteria

The participant eligibility criteria are presented in Table 2. Feasibility of both clinicians' and service users' criteria was assessed through constant monitoring of the recruitment process. The recruitment rates were regularly assessed and any recorded issues discussed with the local clinicians and researchers, as well as the TACK Programme Management team, with the aim to modify the study procedures, including the eligibility criteria, if required.

Assessing feasibility of outcome evaluation and variability of outcome measurement

Feasibility of outcome evaluation

The study assessed feasibility of using the instruments selected to measure a range of health, social and cost-related outcomes in the main cRCT. All the measures were well-established and validated for use with service users diagnosed with depression. The selection of outcomes was based on previous depression research, and trials testing DIALOG + in other service user populations [17]. The SPIRIT statement of the enrolment,

Table 2 Participant eligibility criteria

Inclusion Criteria	Exclusion criteria
Service Users	
18–80 years old	Primary problem of current substance misuse
Clinical diagnosis of depression with a duration of illness of at least 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 language	
Low subjective quality of life (as 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 health care professional	No regular contact with service users with depression
Experience of working in health care for at least six months	
Experience of treating individuals with chronic depression (defined as within the last 6 months)	
No intention to leave the post within the next 6 months	

interventions and assessments is presented in Table 3 [28].

As a part of establishing the feasibility of the selected outcome measures, we proposed and assessed Subjective Quality of Life (SQoL) as the primary outcome. SQoL was measured by the Manchester Short Assessment of Quality of Life scale (MANSA) [29]. This is a sixteen-item scale, with 12 items measuring satisfaction with different areas of life on a seven-point Likert scale, and 4 items assessed with a Yes/No response. The same measure was also used as a screening tool to ensure that potential participants had a SQoL score < 5, thus meeting this inclusion criterion.

The following proposed secondary outcomes were also assessed:

- Depression symptoms measured via observer ratings on the Montgomery-Åsberg Depression Rating Scale (MADRS) [30], and self-reported ratings on the Beck Depression Inventory (BDI-II) [31]. The MADRS was used as the second screening tool to ensure participants had a minimum required level of symptoms of depression (MADRS ≥ 10).
- Capability of the general adult population measured on the ICECAP-A [32].
- Health related quality of life measured by the EQ-5D-3L instrument [33].
- Treatment satisfaction measured on the Client Satisfaction Questionnaire (CSQ-8) [34].
- Costs of health service use, prescribed medication, productivity lost, burden on family and friends, and contact with criminal justice, assessed on an adapted Client Service Receipt Inventory (CSRI) [35].

Sociodemographic and clinical information was collected via a self-report questionnaire administered as part of the baseline CRF.

Two clinician-rated (observer) secondary measures were included in the assessments:

- Health of the Nation Outcome Scale (HONOS), a 12-item clinician-rated instrument developed to measure health and social care outcomes in secondary care mental health services for working-age adults (18–65 years) [36].
- Global Assessment of Functioning (GAF), an observer rated numerical scale (0–100) developed to assess the social, occupational, and psychological functioning of an individual [37].

A process measure was completed at 6 months by the service users from the intervention arm only to assess their experience of receiving the DIALOG + intervention:

- The 'DIALOG + Experience Questionnaire' is a bespoke measure purposefully co-produced with the TACK Programme Lived Experience Advisory Panel (LEAP) to assess service users' experience of receiving DIALOG + as part of routine care. This measure assesses 7 key aspects of experience as identified by the experts by experience: usefulness of DIALOG +; ease of using DIALOG +; satisfaction with treatment while receiving DIALOG +; how much they liked the DIALOG + process; impact on clinical relationship; ease of using a tablet; and treatment preference. The responses were reported on a Likert style scale from 0 to 4. The measure was administered by an unblinded researcher after the 6-month quantitative assessment was completed.

The level of completion of the included outcome measures was monitored via communication with the local sites. Researchers also completed a brief evaluation form to identify any issues they may have encountered during

Table 3 SPIRIT statement: schedule of enrolment, interventions, and assessments

	STUDY PERIOD			
	Enrolment	***Allocation***	***Post-allocation***	
TIMEPOINT**	$-t_1$	**0**	t_1 *(Baseline)*	t_2 *(6 months)*
ENROLMENT				
Eligibility screen	X			
Informed Consent	X			
Manchester Short Assessment of Quality of Life (MANSA)	X			X
Montgomery-Åsberg Depression Rating Scale (MADRS)	X			X
Allocation		X		
INTERVENTIONS				
DIALOG+			———	———
TAU + DIALOG Scale			———	———
ASSESSMENTS				
Beck Depression Inventory (BDI-II)			X	X
Health of the Nation Outcome Scale (HONOS)			X	X
Global Assessment of Functioning (GAF)			X	X
ICECAP-A			X	X
EuroQol-5 Dimension (EQ-5D-3L)			X	X
Client Satisfaction Questionnaire (CSQ-8)			X	X
Client Service Receipt Inventory (CSRI)			X	X
DIALOG+ Experience Questionnaire				X (Intervention arm only)

data collection, with the view of addressing them in the main cRCT.

As MANSA and MADRAS were used for screening eligibility of service users we expected these measures to be completed by 100% participants at baseline. It was expected that at least 80% of the sample would complete the primary outcome (MANSA) at 6-month follow up. No overall formal completion criteria were set for the secondary outcome measures.

Variability of outcome measurement

To assess the variability of outcome measurement we conducted the following series of analyses. Baseline socio-demographic characteristics were summarised by trial arm using descriptive statistics. Quantitative outcome data were summarised descriptively focusing on estimation of effect and variability of outcome measurement rather than significance testing. For continuous factors we calculated means, standard deviations (SD), confidence intervals (CI) and effect sizes within each trial arm over the two time points (baseline and 6 months), while numbers and percentages were reported for categorical factors. Differences between the two arms were reported, but *p*-values were not calculated or quoted. An estimate of the intra-cluster correlation coefficient (ICC) was calculated for the suggested primary outcome (MANSA) using standard analysis of variance techniques [38]. All analyses were conducted by intention-to-treat meaning that participants were analysed according to the treatment group they were randomised to irrespective of whether they received the allocated treatment and/or adhered to the protocol. All analyses were carried out using STATA [39].

Assessing acceptability of recording methods for evaluating treatment fidelity

As evaluation of treatment fidelity was envisaged as a part of the main cRCT design, acceptability of recording DIALOG + sessions was assessed in the present study. This was achieved by asking potentially interested clinicians and service users on the consent forms if they would agree for one of their treatment sessions to be audio or video-recorded. Acceptability was operationalised as more than 50% of the total number of consented participants in both samples agreeing to some form of recording whether it was video, audio or both, depending on their preference.

Assessing acceptability of the adapted intervention

Prior to the feasibility cRCT we explored the acceptability of the DIALOG+ intervention for service users with chronic depression and clinicians who treat them in a qualitative study which followed a 3-month period of non-randomised testing in community-based services [40]. When asked if they would use the DIALOG + intervention in the future, 15 out of 18 service users (83.3%), and 13 out of 15 clinicians (86.6%) expressed interest in using it again.

In the present study we assessed the acceptability of the intervention to the participants in the randomised trial where biases linked to IT confidence are less likely, by using a similar method of establishing openness to future use. As a part of the qualitative evaluation, both service users and clinicians were asked a simple closed question on whether they would use the DIALOG + intervention again in the future and their responses recorded. Based on the previous findings in a similar setting we defined acceptability as 80% or more participants, both service users and clinicians, expressing interest in using DIALOG + again.

To further explore acceptability from the perspective of service users, we used the DIALOG+ Experience Questionnaire (previously described above). The measure was administered to service users allocated to the intervention group only. The acceptability was operationalised as at least 50% of participants being explicitly satisfied (score ≥ 3) with each aspect of the intervention as defined by 7 items of the DIALOG + questionnaire. This was intended as a guidance to identify any potentially problematic areas for further exploration in the qualitative evaluation.

Qualitative evaluation

All clinicians from the DIALOG + arm ($n = 8$) and a purposive subsample of service users from their clusters (approximately $n = 10$) were planned to be interviewed to explore their experiences of the intervention. The aim was to interview service users taking into the account their gender and age composition and including those with both positive and negative experiences of the DIALOG + treatment, based on responses to the DIALOG + Experience Questionnaire.

The service user topic guide was developed in collaboration with experts by experience from the TACK Programme LEAP. The guide covered perceived benefits and downsides of DIALOG + as well as any suggestions for improvement. The clinician topic guide covered similar topics but also explored the ease of integration into and compatibility of DIALOG + with the clinician's routine practice, clinical systems and their views on the training received. The qualitative interviews were conducted by the trial researchers at either participants' homes or NHS premises, according to their preferences.

All interviews were audio-recorded and transcribed verbatim with any identifying information removed. The transcripts were analysed using thematic analysis, broadly following the 6-step approach outlined by Braun and Clarke [41] and facilitated by qualitative software

NVivo v12 [42]. The analysis was conducted by an analytic team consisting of three TACK study researchers (AM, PM, LJ) and three members of the LEAP team (NB, SH, JH, see Acknowledgements). AM and LJ are researchers with a professional background in psychology, while PM is an academic psychologist with expertise in qualitative methods. The lived experience experts supported the analysis of service user data as we felt it was important that their personal perspectives were included in the process. They had previous research experience from being involved in other studies and also received a thematic data analysis training course delivered by the research team.

The initial lists of codes were created separately for the clinician data and service user data. To facilitate this process, AM read and re-read all the transcripts to ensure familiarisation with the data, while generating ideas for coding. The lists of codes were presented to and refined with the wider analytic team, resulting in two coding frames which were subsequently applied by AM to the clinicians' and service users' transcripts. The clinicians' transcripts were double- coded by a researcher DM, while coding of service users' transcripts was discussed with the LEAP members of the analytic team who supported this process.

The next stages of analysis involved an iterative process of searching for patterns in coded data, development of broader categories and their refinement and grouping into conceptual themes. These steps were carried out separately for the two data sets, however, emerging data patterns were regularly compared and contrasted by the analytic team. Since the participating clinicians and service users reported similar or complimentary views on the experience of using DIALOG+, the categories and themes from the two datasets were gradually merged and both perspectives combined into several overarching themes. We believe that this integration added meaning and depth to the themes while avoiding repetition. The developing themes were periodically presented to and discussed with a wider TACK LEAP group, with their feedback integrated into the analysis.

Public and patient involvement

A LEAP was convened at the start of the research programme and consisted of 8 experts by experience who have either personal experience of having chronic depression or caring for a person who does. The panel met regularly (3 times a year) throughout the feasibility study.

The LEAP members were involved in co-producing service-user facing documents, such as the participant information sheets and consent forms, and the service user topic guide for the qualitative study. They also led on the development of the DIALOG+ Experience Questionnaire. Three LEAP members were additionally trained in thematic analysis to support the qualitative evaluation [43].

Results

Feasibility of recruitment and retention strategies for the definitive cRCT

Recruitment of clinicians

Twenty clinicians were initially consented to the trial, however, only 11 of them were randomised. These drop-outs were primarily caused by organisational-level difficulties in one of the sites where restructuring of care-pathways was taking place. The clinician recruitment rate was therefore 92% of the estimated sample and categorised as "good" (>80%) for the purposes of the feasibility trial.

Recruitment of service users

Recruitment and retention of service users is outlined in the CONSORT diagram (Fig. 1) [44]. We recruited 36 out of an originally estimated sample size of 48 service users. This represented a service user recruitment rate of 75%. 49 service users were identified by clinicians from their caseloads and screened for eligibility. All 36 participants who consented and were eligible based on the screening criteria were duly randomised into the trial. One service user was approached for participation in error (post-randomisation of the cluster) by their clinician but was subsequently allowed to join the intervention cluster for ethical reasons as they expressed a strong wish to participate.

The number of recruited service users fell short of the total sample target. However the recruitment rate of 75% was seen as "acceptable", albeit with a need for modifications to the recruitment strategy for the definitive trial as the causal issues were clearly identified. As with the clinician sample, lower than expected recruitment was related to treatment pathway restructuring in one of the sites, with potentially eligible service users being diverted to clinical teams not involved in the study. Based on these findings, the procedures for the main cRCT design were modified to include robust pre-engagement checks for all services interested in participating in the trial.

Randomisation and allocation of the clusters to the trial arms

The randomisation procedure resulted in 11 allocations. Eight clusters with 25 service users were allocated to the DIALOG+ intervention arm and 3 clusters with 11 service users to the active control arm. The size of clusters varied from 2 to 5 participants, with an average of 3.3 service users per cluster (slightly lower than the originally predicted average of 4 per cluster). Previously mentioned organisational-level difficulties caused delays in the completion of some clusters and subsequent randomisations. This had an impact not only on the number of service

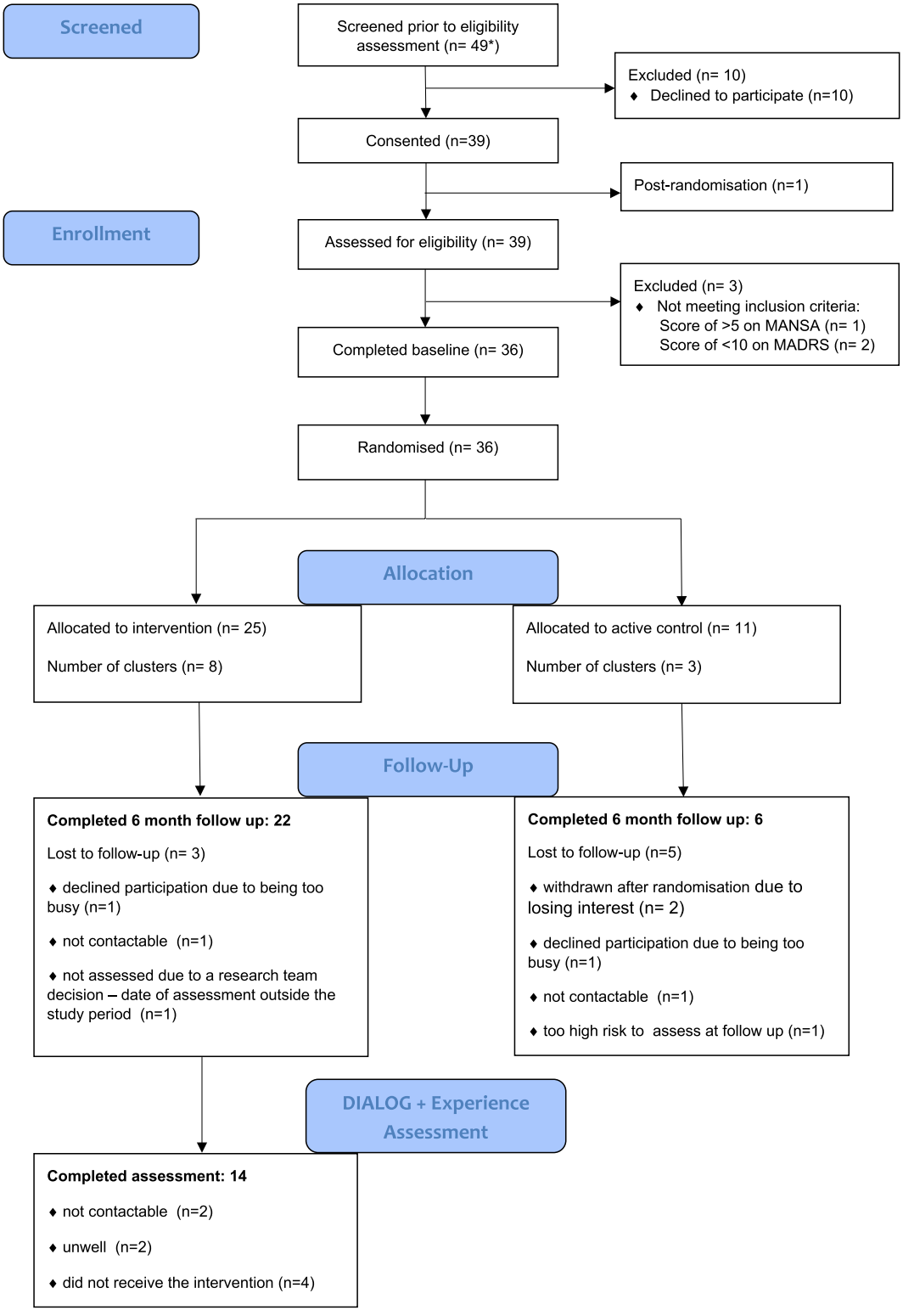

Fig. 1 Consort diagram

users recruited but in some cases their willingness to continue with the study. Two service users lost interest to participate after a prolonged wait and withdrew immediately after randomisation, resulting in the loss of the whole cluster.

Participant retention rates

Out of 36 service user participants randomised, 28 completed their follow-up assessment at 6 months. An "acceptable" retention rate of 77.8% was achieved for the overall sample despite the prolonged recruitment period. 22 participants (88%) in the DIALOG + arm completed a follow-up, while the proportion was lower in the active control (54.5%), partly due to the early withdrawal of the whole cluster in this arm. The service user from the intervention arm who was recruited in error after randomisation was not assessed at 6 months based on the recommendations from the supporting Clinical Trials Unit. The last three assessments were conducted over the phone, not face-to-face, due to the start of the COVID-19 pandemic.

Participant characteristics

The participating clinicians' socio-demographic and professional characteristics are displayed in Table 4, and the service users' characteristics in Table 5. Data are presented per trial arm. The characteristics of the participants withdrawn from the active control cluster immediately after randomisation are not included.

Table 4 Socio-demographic and professional characteristics of clinicians

Clinician characteristics at baseline	Treatment arms	
	DIALOG + Intervention	Active Control
	N = 8	*N* = 2
Age (years, n (%))		
< 35	1 (12.5)	1 (50)
35–49	5 (62.5)	1 (50)
50–65	2 (25.0)	0
Sex		
Male, n (%)	2 (25.0)	2 (100)
Female, n (%)	6 (75.0)	0
Professional background		
Psychiatric nurse, n (%)	4 (50.0)	1 (50.0)
Social worker, n (%)	1 (12.5)	1 (50.0)
Psychiatrist, n (%)	2 (25.0)	0
Mental health workers, n (%)	1 (12.5)	0
Ethnicity		
White British/Irish/Other, n (%)	3 (37.5)	1 (50.0)
Black/Black British-African, n (%)	4 (50.0)	1 (50.0)
Other, n (%)	1 (12.5)	0
Mental health care experience (years; mean (SD))	14.25 (12.5)	10 (11.3)

Feasibility of participant eligibility criteria

The feasibility of eligibility criteria for both clinicians and service users was monitored at each site in relation to the screening and recruitment rates. We established that the original criteria were too narrow for both groups requiring modifications for the main cRCT.

Regarding clinicians, we found that some staff members who regularly see service users with chronic depression in community-based mental health services and who would be well-placed to deliver DIALOG +, e.g. support workers, often did not have a specific mental health or health care qualification and were therefore being needlessly excluded. Additionally, several consented clinicians withdrew due to the lack of potentially eligible service users on their caseloads. The eligibility criteria were consequently updated to include any person working as a mental health or healthcare professional, with a requirement for the interested clinicians to have at least 4 potentially eligible participants on their caseload at the time of consent, as a way of "pre-screening".

For service user participants, establishing a diagnosis of chronic depression was often challenging due to inconsistent indexing and poor record keeping on the electronic medical records. This meant that individuals with the relevant long-term symptoms were often regarded as ineligible because they did not have a specific recorded diagnosis or F-code. To adequately capture participants from this service user group, the eligibility criteria were modified to be more inclusive. The updated criteria stipulate that a potential participant is eligible if they have a clinical presentation consistent with chronic depression and/or low mood, of at least 2 years duration, based on the judgment of their clinician, regardless of them having a recorded diagnosis or not.

Feasibility of outcome evaluation and estimating variability of outcome measurement

Completion of outcome measures

The local researchers who administered the outcome measures reported that the quantitative assessments lasted between 60 and 90 min per visit, depending on the needs of the individual participants.

The clinical outcome measures MANSA, MADRS, and BDI-II were completed by 100% of assessed participants at both baseline and 6-months, in both trial arms. However, as suicidal thoughts were frequently reported (Item 10 on the MADRS, and Item 9 on the BDI-II explicitly ask about suicidal ideation and plans), a standard operating procedure (SOP) was developed to deal with such disclosures. The purpose of this SOP was to address researchers' conduct towards service users in such cases and help them identify when to inform the treating clinicians. Additionally, the need to break confidentiality should such disclosures be made during research assessments

Table 5 Socio-demographic characteristics of service users

Service user characteristics at baseline	Treatment arms	
	DIALOG + Intervention	Active Control
	N = 25	*N* = 9
Age (years; mean (SD))	45.9 (14.6)	43.7 (8.0)
Sex		
Female, n (%)	18 (72.0)	4 (44.4)
Male, n (%)	7 (28.0)	5 (55.6)
Marital status		
Single & unmarried, n (%)	17 (68.0)	7 (77.8)
Married & cohabiting, n (%)	2 (8.0)	2 (22.2)
Separated & divorced, n (%)	6 (24.0)	0
First language		
English, n (%)	19 (76.0)	7 (77.8)
Other, n (%)	6 (24.0)	2 (22.2)
Education		
Primary education or less, n (%)	2 (8.0)	0
Secondary education, n (%)	7 (28.0)	0
Tertiary & Further education, n (%)	4 (16.0)	4 (44.4)
Higher Education, n (%)	12 (48.0)	5 (55.6)
Accommodation		
Independent accommodation, n (%)	23 (92.0)	7 (77.8)
Supported accommodation, n (%)	2 (8.0)	2 (22.2)
Living situation		
Living alone, n (%)	9 (36.0)	1 (11.1)
Living with a partner or family, n (%)	11 (44.0)	4 (44.4)
Living with friends, n (%)	1 (4.0)	2 (22.2)
Living in shared accommodation n (%)	4 (16.0)	2 (22.2)
Employment		
Paid or self-employment full time, n (%)	6 (24.0)	2 (22.2)
Paid or self-employment part time, n (%)	2 (8.0)	1 (11.1)
Unemployed, n (%)	14 (56.0)	6 (66.7)
Student, n (%)	2 (8.0)	0
Retired, n (%)	1 (4.0)	0
Receiving state benefits		
Yes, n (%)	16 (64.0)	5 (55.6)
No, n (%)	9 (36.0)	4 (44.4)
Ethnicity*		
White British	11 (44.0)	2 (22.2)
White Other	3 (12.0)	2 (22.2)
Black/Black British-African, n (%)	1 (4.0)	1 (11.1)
Black/Black British-Caribbean, n (%)	3 (12.0)	1 (11.1)
Black Other, n (%)	0	1 (11.1)
Asian/Asian British-Bangladeshi, n (%)	1 (4.0)	0
Asian/Asian British-Pakistani, n (%)	1 (4.0)	1 (11.1)
Asian/Asian British-Other, n (%)	2 (8.0)	0
Mixed White & Asian, n (%)	2 (8.0)	0
Mixed White & Black, n (%)	0	1 (11.1)
Other, n (%)	1 (4.0)	0

was made explicit in the participant information sheet and the consent form for the definitive cRCT.

The CSQ-8 had a lower completion rate with 16 (64%) participants from the DIALOG + arm completing the measure at baseline and 11 (50%) at 6-months, while 100% of participants from the active control arm completed this measure at both time points. The lower rate of completion in the intervention arm was due to a protocol breach in one site where a superseded version of the

case report form (CRF), without the CSQ-8, was used by a local researcher.

The health economic measures of ICECAP-A and EQ-5D-3L were completed by 100% of participants at both trial time-points, in both trial arms.

CSRI is a widely used measure recording, in detail, health care service use and informal care. Due to the complexity of the measure, items were separated into main questions and sub-questions for the purpose of calculating completion rates. Of the main questions 100% were completed by service user participants, and corresponding sub-questions by at least 50% of them at both baseline and 6-months, and in both trial arms. No prespecified completion criteria were set for CSRI due to its complexity and length. However, as all the main questions across different sections were completed by 100% of service user participants, we were satisfied that self-reported resource-use data provided by the participants was sufficient for the purposes of our study, without the need for researchers to access medical records. Based on the feedback from local researchers, we created a list of common antidepressant medications as a memory aide to increase accuracy of recalled information about medication usage.

The participating clinicians completed both HONOS and GAF at baseline for 14 (56%) service users in DIALOG + and 3 (33%) in the active control arm, while at 6-months the completion rates were 7 (32%) vs 4 (67%) for HONOS and 6 (27%) vs 3 (33%) for GAF. In addition to low completion rates, the feedback from the participating clinicians and the local researchers indicated that completing HONOS and GAF measures was onerous within the given timeframe. Consequently, both instruments, which are complex, multi-item measures, were replaced by a single-item (clinician rated severity of illness) from the Clinical Global Impression Scale (CGI) [45] for the definitive trial.

Fourteen out of 18 service users (77.8%) in the DIALOG + trial arm who received the intervention completed the DIALOG + Experience questionnaire after the 6-month follow-up.

Findings on variability of outcome measurement

Table 6 shows the values of the outcome measures per trial arm at baseline and 6 months. Two service users from the active control arm who withdrew from the study immediately after randomisation were excluded from the analysis. As the study was designed to assess the

Table 6 Scores on outcome measures at baseline and 6-month follow-up

Outcome Measures		DIALOG + Intervention		Active Control	
		Baseline *N* = 25	6-month *N* = 22	Baseline *N* = 9	6-month *N* = 6
MANSA	mean (SD)	3.4 (0.8)	4.2 (1.1)	3.2 (0.6)	3.6 (0.9)
	95% CI	(3.09, 3.71)	(3.74, 4.66)	(2.81, 3.59)	(2.88, 4.32)
MADRS	mean (SD)	29.7 (7.7)	22.1 (10.1)	32.1 (11.7)	34.5 (7.5)
	95% CI	(26.7, 32.7)	(17.9, 26.3)	(24.5, 39.7)	(28.5, 40.5)
BDI-II	mean (SD)	33.9 (10.8)	25.8 (14.5)	37 (10.2)	39.7 (9.5)
	95% CI	(29.7, 38.1)	(19.7, 31.9)	(30.3, 43.7)	(32.1, 47.3)
ICECAP-A	mean (SD)	14.3 (2.4)	12.8 (3.7)	14.9 (2.6)	14.5 (1.1)
	95% CI	(13.4, 15.2)	(11.3, 14.4)	(13.2, 16.6)	(13.6, 15.4)
CSQ-8	mean (SD)	25.9 (4.9)	24.7 (6.8)	26.1 (4)	23.7 (5.2)
EQ-5D-3L Mobility	Level 1, n (%)	12 (48)	13 (59.1)	6 (66.7)	4 (66.7)
	Level 2, n (%)	13 (52)	9 (40.9)	3 (33.3)	2 (33.3)
	Level 3, n (%)	0	0	0	0
EQ-5D-3L: Self-care	Level 1, n (%)	16 (64)	15 (68.2)	4 (44.4)	2 (33.3)
	Level 2, n (%)	8 (32)	7 (31.8)	5 (55.6)	4 (66.7)
	Level 3, n (%)	1 (4)	0	0	0
EQ-5D-3L: Usual Activities	Level 1, n (%)	6 (24)	8 (36.4)	2 (22.2)	2 (33.3)
	Level 2, n (%)	15 (60)	12 (54.6)	6 (66.7)	4 (66.7)
	Level 3, n (%)	4 (16)	2 (9.1)	1 (11.1)	0
EQ-5D-3L: Pain/Discomfort	Level 1, n (%)	6 (24)	9 (40.9)	3 (33.3)	3 (50)
	Level 2, n (%)	13 (52)	9 (40.9)	3 (33.3)	1 (16.7)
	Level 3, n (%)	6 (24)	4 (18.2)	3 (33.3)	2 (33.3)
EQ-5D-3L: Anxiety/Depression	Level 1, n (%)	0	6 (27.3)	0	0
	Level 2, n (%)	18 (72)	10 (45.5)	3 (33.3)	3 (50)
	Level 3, n (%)	7 (28)	6 (27.3)	6 (66.7)	3 (50)
EQ-5D-3L: VAS	mean (SD)	42.2 (22.8)	49.3 (27.4)	31.6 (18.4)	40.5 (12.5)

*CSQ-8 completed by 16 participants at baseline and 11 at 6-months

feasibility of conducting a future definitive cRCT and was not sufficiently powered, no formal significance testing was carried out.

Self-reporteded SQoL scores at baseline were low in both trial arms, with the mean MANSA score being below the mid-point of 4 (DIALOG+ 3.4 (SD = 0.8) vs active control 3.2 (SD = 0.6)). The mean MANSA scores at 6 months were 4.2 (SD = 1.1) for the participants in the DIALOG + arm and 3.2 (SD = 0.6) for those in the active control. Although the sample was not sufficiently powered to show a difference between groups, the intra-group score change indicated increased level of SQoL at 6-months in the intervention trial arm (M = 4.2; 95% CI [3.74, 4.66]) as opposed to the active control where no such increase was recorded (M = 3.6; 95% CI [2.88, 4.32]). The effect size, measured by Cohen's *d* at 6 months, was *d* = 0.59, indicating a medium effect size. The estimate of the ICC for MANSA as the primary outcome at 6-months had an average value of about 0.024 (2.4%), with a range of (0.0181 to 0.031) which indicates a very low correlation within the clusters.

The mean baseline scores on MADRS were similar in the DIALOG + (29.7 (SD = 7.7)) and active control arm (32.1 (SD = 11.7)), indicating moderate levels of depression symptoms in both groups at entry into the study. At 6-month follow up, the mean scores were 22.2 (SD = 10.1) in the DIALOG + arm, and 34.5 (SD = 7.5) in the active control arm. As before, although the sample was not powered to detect a difference between trial arms, the findings indicate a decrease in the observer-rated depressive symptoms scores of 7.6 points (95% CI [17.9, 26.3]) in the intervention arm, with no such decrease indicated for the active control (95% CI [28.5, 40.5]). At six months, the effect size was *d* = −1.39, indicating a large effect.

The mean baseline scores on BDI-II, the self-reported measure of depressive symptoms, were 33.9 (SD = 10.8) in the DIALOG + arm and 37 (SD = 10.2) in the active control arm. At 6-months, the mean scores were 25.8 (SD = 14.5) and 39.7 (SD = 9.5) respectively. The findings indicate that the participants in the DIALOG + arm had lower self-reported levels of depressive symptoms at 6-months based on a mean intra-group score change of 8.1 points (95% CI [19.7, 31.9]), with no such decrease recorded for the active control group (95% CI [32.1, 47.3]). The effect size at six months was *d* = −1.13, again indicating a large effect of DIALOG + on reducing depression symptoms.

For those who completed CSQ-8 as a measure of treatment satisfaction, the baseline scores were 25.9 (SD = 4.9) in the DIALOG + and 26.1 (SD = 4) in the active control arm. At 6-months point, the mean scores were 24.7 (SD = 6.8) in the intervention and 23.7 (SD =5.2) in the active control arm, indicating no change in satisfaction in either arm.

Reductions in the MADRS and BDI-II mean depression scores in the DIALOG + arm were also reflected in the movement of participants between the categories of the Anxiety/Depression question of the EQ-5D-3L. While none of the service users in the DIALOG + arm described themselves as "not anxious or depressed" at baseline, 27% (*n* = 6) did so at 6 months. The number of those in the "moderately anxious or depressed" category was reduced from 72% (*n* = 18) to 46% (*n* = 10). In contrast, no participants in the Active Control arm described themselves as "not anxious or depressed" at either baseline or 6-months, while the number of those "moderately anxious or depressed" increased in terms of percentage from 33.3% to 50%. However, the number of those selecting category "extremely anxious or depressed", stayed similar in the DIALOG + arm (28%, *n* = 7 vs 27.3%, *n* = 6), but reduced somewhat in the active control arm (66.7%, *n* = 6 vs 50%, *n* = 3).

ICECAP-A mean scores were similar in both groups and at both study time-points. The mean scores at baseline were 14.3 (SD = 2.4) for the DIALOG + arm and 12.8 (SD = 3.7) for the active control arm, while the respective scores at 6-months were 12.8 (SD = 3.7) and 14.5 (SD = 1.1).

Acceptability of recording methods for evaluating treatment fidelity

Seventeen consented clinicians (85%) agreed for some of their sessions to be audio or video recorded. Twenty-six consented service users (66.7%) agreed for their sessions to be audio or video recorded, with 8 (2.1%) opting for audio-recoding only. As more than 50% of consented participants in both samples agreed to one or both forms of recording, the chosen methods were deemed acceptable for assessing DIALOG + treatment fidelity in the main trial. The rate of agreement per trial arm is not presented as this question was asked prior to randomisation.

Acceptability of the adapted intervention

Preferences for future use

When asked as a part of the qualitative evaluation whether they would be willing to use DIALOG + in future, 6 out of 7 service users (85.7%) stated preference for doing so. Only one service user felt that DIALOG + was not at all useful for their needs but observed that it could be beneficial for others. Five out of 6 clinicians (83.3%) reported that they would use DIALOG + again in at least some of their sessions, with only one preferring not to use the intervention at all. This clinician felt that they already apply similar therapeutic principles in their practice and that using a tablet made their conversations with service users less personal and less spontaneous. As more than 80% of clinicians and service users stated that they would use the DIALOG + intervention again, reflecting

our previous findings on the future use preferences in the non-randomised study [40], the intervention was deemed acceptable for use as part of the definitive cRCT.

DIALOG+ experience questionnaire

Responses to the DIALOG + Experience Questionnaire are presented in Table 7.

Twelve (85.7%) of the participants who completed this measure were explicitly satisfied with their treatment whilst receiving DIALOG +, 11 (78.6%) liked the DIALOG + process, 9 (64.3%) found the tablet easy to use, 8 (57.2%) preferred treatment with DIALOG +, and the same percentage found it useful; and finally, 7 (50%) reported a positive impact on their relationship with the clinician. These findings further emphasise the acceptability of the intervention as at least 50% of the assessed service users reported explicit satisfaction (score ≥ 3) with each of the 7 aspects of the questionnaire developed by the study LEAP members.

Qualitative evaluation findings

All eight clinicians who were allocated to the intervention arm were approached to take part in an individual semi-structured interview. Six of them were interviewed (3 from each participating Trust), while the remaining 2 clinicians were not contactable. Five of the interviewed clinicians were female and 1 male. Three clinicians were community psychiatric nurses, 2 were psychiatrists and 1 was a social worker. Four interviews were conducted face-to-face and 2 over the phone due to COVID social distancing policies at the time. The interviews lasted between 34 and 64 min.

Fourteen service users who received DIALOG + and were contactable at the point of the 6-month follow-up assessment, were invited to participate in a qualitative interview. Seven of them were interviewed, 3 declined, 2 did not respond after the initial approach, and 2 did not feel well enough to take part. Five participants were female and 2 male. Six interviews were conducted face-to-face and one over the phone. The interviews lasted between 41 and 75 min.

Findings on the experience of using DIALOG+

Most interviewed service users and clinicians reported a mixture of positive and negative aspects of using DIALOG + and their views have been combined into five overarching themes, outlined here.

1. Clarity & focus

DIALOG + was viewed as helping service users to identify the most pressing issues they needed to work on at that point in their recovery journey. Thinking about and rating different areas of life and treatment, and not just mental health, was instrumental in separating issues and understanding priorities.

> *SU: "... you wouldn't normally rate your life, but the questions make you think about it more... Because you think about it and it's like, well actually, I do have a lot of trouble with this. It's very difficult, very difficult for me to do that. So, some people know where they have problems, other people maybe not so much. And then you can see which are the worst things for you, which affect you the most." BHP10_female.*

Focusing on a small number of areas and specifying concrete actions to address them made the process of finding solutions and acting on them more manageable. This approach also helped clinicians gain a more comprehensive picture of the service users' life, leading to more targeted treatment decisions.

> *C: "...that linkage, that interconnection between the different aspect of their lives how that affects their mental health. So that was really very helpful." BHC08_female*

There were some exceptions, however, with one service user finding the DIALOG + process redundant as they already knew their priorities, while one clinician felt they already applied the same principles without having to use technology or a structured intervention.

Table 7 DIALOG+ Experience Questionnaire

Aspect of experience of using DIALOG +	Explicitly satisfied (score ≥ 3) N (%)	Neutral (score = 2) N (%)	Explicitly dissatisfied (score ≤ 1) N (%)
1.How useful did you find DIALOG +?	8 (57.2%)	4 (28.6%)	2 (14.3%)
2. How easy did you find it to use DIALOG +?	9 (64.3%)	2 (14.3%)	3 (21.4%)
3. How satisfied were you with your treatment whilst using DIALOG +?	12 (85.7%)	1 (7.1%)	1 (7.1%)
4. How much did you like going through the process of DIALOG +?	11 (78.6%)	1 (7.1%)	2 (14.3%)
5. Did receiving the DIALOG + affect the relationship with your clinician?	7 (50%)	5 (35.7%)	2 (14.3%)
6. How easy was it to use the tablet device during the session? *	9 (64.3%)	1 (7.1%)	2 (14.3%)
7. Did you prefer DIALOG + to the treatment you have received previously?	8 (57.2%)	2 (14.3%)	4 (28.6%)

*2 service users chose not to handle the tablet themselves

2. Changing conversations

Both service users and clinicians talked about the ways in which using DIALOG + changed the way they communicated. The items on the 'DIALOG scale' reminded them about different topics they could potentially discuss, introduced new ones, and initiated important conversations. This process led to richer, more elaborate clinical discussions.

> *C: "I never talked about, specifically about personal safety, for instance. Or, if you feel so isolated and you don't have friends, how much that can impact… I would discuss topics that maybe sometimes we just touched on before but not in that way that we specifically discussed that kind of topics." ELC05_female.*

However, for some participants conversations felt hurried due to having to adhere to the manualised format. They felt unable to have spontaneous discussions and/or address all the issues arising in the session. Some clinicians struggled to keep conversations focused as their service users preferred to talk freely. Using DIALOG + occasionally prolonged discussions which some participants welcomed but others found tiring.

> *SU: "I found it distracting really, because there might be things I wanted specifically to talk about, which I couldn't, because we had to stick to what is on the tablet." ESP03_female*

3. Mapping the journey

Rating satisfaction on the DIALOG scale and comparing the scores from session to session enabled service users to monitor changes in different areas of life and reflect on them. Seeing progress mapped over a period of time gave service users a welcome confidence boost, while deterioration prompted them to think about possible reasons leading to it and how to avoid them in future.

> *SU: "Yeah, in my mind it highlighted someone's attitude or some problem at home… what was the main issue which actually put me back and my progress… last time was I was six, now I'm at three, why am I at three… It was like a clue for me to think…" ELP16_female.*

This process of reflection enabled participants to check if they were on the right track and to rethink treatment strategies as they went along, finding a way forward and giving a sense of direction to their journey.

> *SU: "I think it's a good record of a patient. And, overall, it's helpful. It's like a car driver sitting in a car having an A to Z. It's the same sort of help. It helps you, guides you." ELP17 _male.*

In contrast, a couple of service users felt that rating satisfaction could not capture the complexities of their life situations and/or felt too discouraged by seeing deterioration.

4. Changing the balance of power

The DIALOG + intervention enabled service users to get more involved in care by enabling them to voice their opinions more, work on issues that matter to them, and better understand their personal strengths and resources.

> *SU: "I've had a psychologist in the past and other counselling with IAPT and I think what this (DIALOG +) has done it has given me tools and it structured the conversation and identified what were my priorities and the areas that I needed to work on or where I needed support." BHP22_female.*

Some clinicians learned how to relinquish control and let their patients take the lead, creating a more trusting and equitable relationship.

> *C: "I know I'm good at building therapeutic relationship with the service users but working on this together made the service user feel empowered in the session that they can be trusted to take a lead …" BHC08_female.*

On the other hand, certain aspects of the intervention (such as coming up with own solutions and/or having to complete agreed actions) made some service users feel overwhelmed. They were reluctant to try new behaviours or take on more responsibility, needing more time to adjust to the new way of working,

> *C: "I think I have adopted that laid back approach now that I'm beginning to expect the other people I work with to be taking more leadership in their care. And I'm getting backlash on, I'm not doing it, it's your responsibility. Because I am trying to introduce that and I'm saying to them, the model we're going to be working now is you lead instead of me telling you what to do and when to do it." BHC04_female.*

5. Technology as an aid and a hindrance

Some participants emphasised the importance of sharing the tablet and seeing the information displayed on

Table 8 Trial Design Modifications

Engaging Clinical Sites	
Re-organisation of care pathways in some services led to fewer potentially eligible service users being allocated to the participating clinicians' caseloads resulting in sub-optimal recruitment	Robust pre-engagement checks introduced for services interested in participation to ensure appropriate capacity and support
Eligibility Criteria	
Many service users with symptoms consistent with chronic depression do not have a recorded clinical diagnosis making them ineligible for the study	A clinical diagnosis of chronic depression was replaced by a clinical presentation consistent with the chronic depression and/or low mood, of at least 2 years duration, based on the judgment of the clinician
Some clinicians who frequently care for service users with chronic depression in community-based services do not have a mental health or health care qualification	The qualification related criterion was updated so that any individual working as a mental health or healthcare professional is eligible
Some consented clinicians did not have enough potentially eligible service users on their caseloads	A new criterion was introduced of clinicians required to have at least 4 potentially eligible participants on their caseload at the time of consent
Outcome Measures	
MADRS and BDI-II: A high number of service users reporting suicidal ideation in response to the items assessing suicidal thoughts (MADRS: Item 10; BDI-II: Item 9)	A standard operating procedure was introduced to help researchers respond to service users' distress, and identify when to inform their clinicians; need to break confidentiality and inform clinicians in such cases was made explicit on consent forms
HONOS and GAF: Poor response to the clinician-rated multi-item measures at both baseline and follow-up due to the length of time required to complete them	Both clinician-rated measures replaced by CGI, a simpler single item measure assessing severity of illness
CSRI: Service users sometimes had difficulties to remember the name of the anti-depressant medication they were using	A memory aid was introduced listing the names of commonly prescribed anti-depressants

the screen. This shared visual reference point contributed to the service users' awareness of their current strengths and difficulties and their motivation to make change. It also made treatment more transparent, with a better sense of continuity of care.

> *SU: "...could see things happening, I could see, instead of just generalising stuff I could see things happening on a screen, it was my wellbeing, my mental health, my, all the activities that were on there ... it was more concrete, it was more evidence that I could see..." ELP22_male.*

However, a few participants felt that the use of tablets in the clinical space impaired the natural flow of conversations and made them more impersonal because of time spent looking at the screen. Reduced face-to-face contact negatively impacted on their sense of rapport. Several clinicians encountered difficulties with using a tablet or navigating the DIALOG app, causing some frustration for their patients.

> *SU: "I did not like it because she was looking at the tablet a lot rather than just talking to me. It did not feel as personal as just sitting there talking face-to-face...I prefer talking just without the tablet..." ESP03_female.*

Discussion

This study sought to evaluate the feasibility of conducting a definitive cRCT to investigate the clinical- and cost-effectiveness of DIALOG + in treating service users with chronic depression. The findings indicate that, with some modifications, it is feasible to conduct the planned trial within this service user group.

Modifications to the definitive trial design

The modifications introduced to the definitive trial design are summarised in Table 8. They have been described in more detail in the trial protocol [46].

DIALOG + is intended to structure already occurring routine appointments, with no additional clinician time required, however, implementation of the intervention did encounter some organisational-level barriers. The restructuring of treatment pathways in one of the participating Trusts was identified among the factors causing sub-optimal recruitment and drop-outs. To pre-empt such issues in future, more robust pre-engagement checks were introduced for mental health services interested in participation. These were deemed necessary to establish a more nuanced picture of the organisational capacity and capability of clinical teams and secure comprehensive management-level support for research implementation. The eligibility criteria for both clinicians and service users were modified to be more inclusive and reflective of the clinical realities of diagnosing and treating service users with chronic depression in community-based mental health services. In particular, establishing an exact diagnosis proved challenging due to inconsistent and/or poor indexing on medical records. To adequately capture the target population, we amended the eligibility criteria from having a specific, recorded diagnosis to having a current clinical presentation consistent with the symptoms of chronic depression and/or low mood, based on the judgment of the treating clinician. A

non-diagnostic approach to recruiting service users with depression was successfully used in previous studies [21] and may be more suited for individuals with long-term & recurrent forms of this disorder who tend to be heterogeneous in treatment history, responsiveness and prognosis [47].

The findings of this study were also incorporated into updated safeguarding procedures, introducing specific protocols for identifying and reporting high level of suicidal ideation and dealing with participant distress in such cases. This was of particular importance because of the subsequent outbreak of COVID-19 pandemic which left many service users participating in the main RCT more distressed than usual.

Recent studies have indicated that complete assessment of depression should include both clinician-rated scales and self-reported measures [48]. The completion rate of the two selected clinician-rated outcome measures (HONOS and GAF) was low at both time-points because of the amount of time required to fill them in. Based on this feedback, they were consequently replaced with a simpler, single item measure (CGI—Severity of illness item) for the definitive cRCT.

Comparison with literature

Participant recruitment in this trial did not reach the originally planned target figures, reaching 92% of the clinician and 75% of the service user sample we aimed for. The finding is not unusual as the difficulties in recruiting individuals with depression into clinical trials are well-documented and influenced by a variety of factors [21, 49]. RCTs in general often fail to recruit to target as shown by the reviews of the UK based trials [50]. The participating clinicians in our study mostly screened their caseloads themselves to identify potentially eligible service users and refer them to the researchers. The available evidence on using this recruitment approach has shown mixed results [21]. A qualitative meta-synthesis of the factors associated with recruiting service users with depression into trials [49] indicated that clinicians often perform a certain level of "gate-keeping", based on their perception of the patient's current "health state" and benefits & risks associated with the intervention tested. Although we did not reach the originally estimated service user sample, it is important to highlight that all service users who consented to and were fully eligible for the trial were randomised despite the delays in this process. 77.8% of the randomised participants completed the follow-up at 6 months. This is equivalent to the average attrition rate of 22% identified by the recent systematic review and meta-analysis of randomised studies of depression treatments [51]. Being able to achieve this level of retention is important considering the pragmatic nature of the present trial and obstacles associated with conducting research in routine care.

Although the trial was not powered to find statistical differences between the trial arms, the intra-group changes of SQOL and depression symptoms between the two time-points were found to be encouraging. The participants in the DIALOG + intervention group had better clinical outcomes at 6-months, as indicated by the higher self-reported ratings of SQoL (MANSA) and the lower level of depressive symptoms on both observer- and service user-rated measures (MADRS and BDI-II). A recent international consensus report suggested shifting the focus of treatment from symptomatic remission to optimising symptom control along with maximising psychosocial function and QOL for difficult to treat depression [47]. As the average length of treatment for depression in our study was 7 years, the above recommendation supports choosing a SQoL measure (MANSA) as a more comprehensive primary outcome for the definitive trial.

The tentative findings from this study are in line with the emerging evidence from small trials conducted in Low- and Middle- income countries (LMICs) [52, 53] showing that DIALOG + is suitable and effective for individuals with depression, can improve SQOL and reduce depressive symptoms. However, as these trials were either non-controlled or did not screen participants for chronicity of depression, a definitive trial is still required to test the clinical and cost-effectiveness of the intervention for those with long-term or recurrent forms of depression.

Over 80% of service users and clinicians from the intervention arm who participated in the qualitative interviews expressed interest in using DIALOG + in future. This corresponds to our initial findings from the exploratory non-controlled testing in community care setting, further emphasising acceptability of the intervention [40]. The benefits and downsides of delivering and receiving the intervention reported by the participants were also reflective of those identified at the exploratory stage. In comparison, the service users from a small LMIC trial similarly found DIALOG + empowering and motivating but reported more practical difficulties to attend the treatment sessions [52].

Taken together, developing evidence indicates that DIALOG + can be applied to people with chronic depression and may potentially improve their clinical outcomes across different measures, both self- and observer- rated. This is of particular importance as chronically depressed service users have historically been at risk of being labelled as "treatment resistant" [3].

Strengths and limitations

The intervention was implemented in routine appointments, which makes the results more generalisable to

other services. The trial design included an active control condition which was delivered with a similar frequency to the experimental one. The level of depressive symptoms required to be eligible for the study was confirmed via an observer-rated, structured MADRS interview. We tested a comprehensive set of outcomes including SQOL, different measures of depression severity, health-related quality of life, treatment satisfaction, and self-reported service use. A measure co-produced with the LEAP specifically to assess the experience of receiving DIALOG + was included in the study. Quantitative assessments were complemented by qualitative exploration of the views of both clinicians and service users.

The study was limited by lower-than-expected recruitment rates, and some protocol deviations which led to a smaller than planned active control group. In addition, clinicians could not be blinded towards their own allocation, with a resulting possibility of performance bias. The trial excluded service users who had insufficient command of English as well as those with a high SQOL and a low MADRS score at baseline. Such patients would be included in routine care so it remains unclear to what extent the findings apply to them.

Conclusion

This study demonstrated that the design and trial procedures are viable as the basis for a large, multi-site, cluster randomised controlled trial to test the effectiveness of DIALOG + for people with chronic depression. However, the findings led to some significant modifications to the trial design, meaning feasibility testing was worthwhile. Data indicated that DIALOG + is acceptable to service users with chronic depression taking part in the randomised trial and may improve their outcomes, which is of great importance given the particularly poor clinical and social consequences of this disorder and the lack of tailored interventions.

Abbreviations

BDI	Beck Depression Inventory
cRCT	Cluster Randomised Controlled Trial
CRF	Case Report Form
CSQ	Client Satisfaction Questionnaire
CSRI	Client Service Receipt Inventory
GAF	Global Assessment of Functioning
HONOS	Health of the Nation Outcome Scale
ICD	International Classification of Diseases
ICECAP-A	ICEpop CAPability measure for Adults
LEAP	Lived Experience Advisory Panel
LMIC	Low-and Middle- income countries
MADRS	Montgomery-Åsberg Depression Rating Scale
MANSA	Manchester Short Assessment of Quality of Life scale
NIHR	National Institute of Health Research
QOL	Quality of Life
RCT	Randomised Controlled Trial
SPIRIT	Standard Protocol Items: Recommendations for Interventional Trials
SQOL	Subjective Quality of Life
TAU	Treatment as Usual

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12888-025-07446-3.

Supplementary Material 1.

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Authors' contributions

Study conception and design: VB, PM. Data acquisition: AM, LJ,PM. Data analysis and interpretation: AM, PM, LJ, VB. Manuscript drafting: AM. Manuscript revision: PM, LJ, VB. All authors reviewed and approved the final version of the manuscript.

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Data availability

The datasets used and analysed in the current study are available from the corresponding author upon reasonable request. The datasets are held in controlled access data storage at the Queen Mary University of London.

Declarations

Ethics approval and consent to participate

The authors confirm that the study protocol and all the associated procedures were reviewed and approved by the Wales Research Ethics Committee 6, NHS Health Research Authority, United Kingdom (ID: 219483). Detailed information about the study was provided to and written informed consent obtained from all participants before taking part in the trial.
This study was conducted in accordance with the principles outlined in the Declaration of Helsinki and its subsequent amendments, ensuring ethical standards in research involving human participants.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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