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Toward a conceptual framework of the working alliance in a blended cognitive behavioural therapy intervention: A qualitative study

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Complete List of Authors:	Doukani, Asmae; London School of Hygiene and Tropical Medicine, Faculty of Epidemiology and Population Health Free, Caroline; London School of Hygiene and Tropical Medicine, Faculty of Epidemiology and Population Health Michelson, Daniel ; University of Sussex, School of Psychology Smith, Sarah; London School of Hygiene & Tropical Medicine, Health Services Research and Policy Araya, Ricardo; King's College London, Health Service and Population Research Department Montero-Marin, J; Dharamsala Institute of Mindfulness and Psychotherapy Cerga-Pashoja, Arlinda; London School of Hygiene and Tropical Medicine, Faculty of Epidemiology and Population Health Kakuma, Ritsuko ; London School of Hygiene and Tropical Medicine, Faculty of Epidemiology and Population Health
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1	Toward a conceptual framework of the working alliance in a blended cognitive behavioural
2	therapy intervention: A qualitative study
3	
4	Corresponding author
5	Asmae Doukani, Research Fellow
6	Faculty of Epidemiology and Population Health, London School of Hygiene and Tropical
7	Medicine, Keppel Street, London, WC1E 7HT, United Kingdom.
8	Email: <u>Asmae.Doukani@lshtm.ac.uk</u>
9	Telephone: +44(0)207 927 2462
10	
11	Co-authors
12	Caroline Free, Professor in Primary Care and Epidemiology
13	Faculty of Epidemiology and Population Health, London School of Hygiene and Tropical
14	Medicine,Keppel Street, London, United Kingdom (Caroline.Free@lshtm.ac.uk)
15	
16	Daniel Michelson, Senior Lecturer in Clinical Psychology
17	School of Psychology, University of Sussex, Pevensey Building, Falmer, Brighton, United
18	Kingdom. (D.Michelson@sussex.ac.uk)
19	
20	Sarah Smith, Associate Professor in Psychology
21	Department of Health Services Research and Policy, London School of Hygiene and Tropical
22	Medicine, Keppel Street, London, United Kingdom. (Sarah.Smith@lshtm.ac.uk)
23	

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2						
3 4	24	Ricardo Araya, Professor in Global Mental Health				
5 6	25	Health Service and Population Research Department, King's College London, De Crespigny				
7 8 9	26	Park, London, SE5 8AF, United Kingdom. (Ricardo.Araya@lshtm.ac.uk)				
9 10 11	27					
12 13 14	28	Jesus Montero-Marin, Senior Researcher				
15 16	29	Dharamsala Institute of Mindfulness and Psychotherapy, Zaragoza, Spain				
17 18	30	(jmonteromarin@hotmail.com)				
19 20 21	31					
22 23 24	32	Arlinda Cerga Pashoja, Research Fellow				
25 26	33	Faculty of Epidemiology and Population Health London School of Hygiene and Tropical				
27 28	34	Medicine, Keppel Street, London, United Kingdom. (Arlinda.Cerga-Pashoja@lshtm.ac.uk)				
29 30 31	35					
32 33 34	36	Ritsuko Kakuma, Associate Professor				
35 36	37	Faculty of Epidemiology and Population Health London School of Hygiene and Tropical				
37 38	38	Medicine, Keppel Street, London, United Kingdom. (Ritsuko.Kakuma@lshtm.ac.uk)				
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41 Abstract

42 Objectives: To examine and adapt a conceptual framework of the working alliance (WA) in
43 the context of a blended (human therapist plus computerised program) cognitive behavioural
44 therapy intervention (b-CBT) for depression.

45 Design: Patient involvement was enlisted to collaboratively shape the design of the project 46 from the onset, before data collection. In-depth semi-structured interviews were carried out 47 with participants who experienced b-CBT as part of a trial in the UK. A thematic analysis was 48 conducted using a constant comparative method informed by grounded theory.

49 Setting: Recruitment was carried out in four psychological primary care services across the
50 UK.

Participants: Nineteen participants from the b-CBT treatment arm of the E-compared trial,
who completed at least one computerised module and face-to-face session, were recruited to
the study.

Results: Qualitative interviews that were guided by WA and SUI input, revealed four themes: (1) A healthcare provider with good interpersonal competencies for building a working relationship with the client ('Bond'); (2) collaborative efforts between the client and the provider to appropriately identify what the client hopes to achieve through therapy ('Goals'); (3) the selection of acceptable therapeutic activities that address client goals and the availability of responsive support ('Task'); and (4) the promotion of active engagement, self-discovery and autonomous problem solving ('Heuristics'). Participants also described how blended delivery by the human therapist and the digital program uniquely and collectively contributed to different WA needs.

63 Conclusions: This study was the first to offer a preliminary conceptual framework of WA in
64 b-CBT, and how such demands can be addressed through blended therapist-digital delivery.

These findings can be used to promote WA in technological design and clinical practice, thereby promoting engagement to b-CBT interventions, and the effective deployment of therapist and digital support resources.

Trial registration: E-Compared Trial, ISRCTN registry, ISRCTN12388725. Registered on 20
March 2015.

Keywords: Working alliance, blended psychotherapy, cognitive behavioural therapy, patient and public involvement.

Article summary

Strengths and limitations of the study

- Patient involvement enabled the project aims to be grounded on the needs and interests of people who have experienced mental illness and service-use, in order to enhance the application of the findings.
- Bordin's working alliance theory was adopted to explore within b-CBT due to the theory's comprehensive description, its' pan-theoretical nature, and its' openness to adaptation in relation to different therapeutic formats.
- The studies' sample is limited to 19 individuals with a primary diagnosis of mildto-moderate depression, largely reporting moderate to high WA, thereby restricting the generalisability of our findings to other clinical presentations.
- Exposure to only one type of digital program, may have influenced participant's experience of WA (e.g. a computerised platform that doesn't work adequately might generate more data on the importance of 'ease of use', than one that does), limiting the breadth of data collected on the working alliance.
- Efforts were made to broaden the reach of the conceptual framework through interview topic guides which were guided by the working alliance theory and patient involvement input, and a data analysis approach which avoided surface level themes, specific to technological design.

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78 INTRODUCTION

Mental disorders impact one in six people in the European Union, resulting in an estimated economic burden of over €600 billion.[1] The treatment gap in the region remains high with 35-50% of people experiencing mental health concerns not accessing treatment.[1] The wide disparity between mental health care needs and access to services has prompted calls for the strategic deployment of technology to facilitate and expand access to mental health services at a lower cost.[2,3] In the past decade, an increasing number of studies have investigated the efficacy of computerised cognitive behavioural therapy (c-CBT), a type of digital intervention that delivers CBT via interactive presentation features.[4] The evidence for c-CBT has demonstrated equal benefits to face-to-face CBT for a range of mental disorders.[4] However, these findings largely hold true when digital psychotherapies are guided by a human facilitator. Higher support from a therapist or another human facilitator appears to be related with better adherence and clinical outcomes.[5]

The effects of human support on engagement with c-CBT raises important questions about mechanisms that support positive change in c-CBT. This has led scholars to consider the applicability of established mechanisms of change derived from conventional psychotherapies. to 'blended' (digital plus human facilitation) formats. Particular interest has centred on the construct of the client-therapist allianceⁱ (therapeutic, working etc.).[6,7] While the concept of the alliance has taken root in a number of therapy approaches, Edward Bordin[8] drew on their commonalities to formulate a pan-theoretical theory called the Working Alliance (WA) originally defined as:

"a formation between the client seeking change and the therapist offering to act as a change agent that incorporated a mutual understanding and agreement about change

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goals and the necessary tasks to move forward these goals along with the establishment of bonds to maintain the partners' work".[8,9]

Here, the 'task' refers to an agreed-upon contract that specifies the activities used to work on the client's goals. 'Goals' entails the exploration and review of what the client wants to achieve in therapy, while the 'bond' relates to the perceived compatibility between the client and the therapist, and the partnership that stems from shared activities.[8,9] Central to Bordin's[8,9] conceptualisation, is the collaboration and consensus between the therapist and the client, in order to promote meaningful engagement with the intervention.

The alliance has consistently been found to predict positive therapeutic outcomes. A keystone meta-analytic review found that the therapeutic alliance accounted for more variance (30%) than the therapeutic technique (15%) and therapy expectancy (15%).[10] This alliance-outcome relationship finding, was mirrored in recent meta-analyses, one of 191 varied therapeutic studies (r = .28 [95% CI: .25 to .30]),[11] and another focusing on CBT interventions for depression (r = .26 [95% CI: .19 to .32]).[12] Despite the emerging era of digitisation, a guiding framework to understand the nature of WA as an agent of change has yet to be developed for blended CBT (b-CBT). While some models of behavioural intervention technologies (BITs) offer valuable behavioural change formalisations for informing intervention design, such models are intended to be broad and do not address the client-provider alliance.[13] Given that healthcare is moving towards a model of symbiotic delivery between human healthcare providers and technology, we aim to understand what the WA demands are in b-CBT, through patient involvement and participant qualitative interviews, to adapt Bordin's[8,9] conceptualisation of WA, for a b-CBT format of delivery.[14]

125 METHOD

A qualitative methodology design was used to gain an in-depth understanding of WA with participants who experienced b-CBT on the E-compared trial.[15] E-compared is a non-inferiority, pragmatic trial that evaluated the cost effectiveness of b-CBT for depression, when compared to usual care, across eight countries in the European region. The b-CBT intervention consisted of 11 sessions, six with a low intensity psychological wellbeing practitioner and a least five at home via a synchronised computerised platform and mobile-application called Moodbuster. The treatment course spanned across 11 weeks. Additional information about the trial and the b-CBT intervention can be accessed from the trial protocol by Kleiboer and colleagues.[15]

135 Participants

E-Compared participants from the UK were invited to take part in qualitative interviews. Trial participants aged 18 years or older with a clinical diagnosis of Major Depressive Disorder were enrolled in the study.[15] People with substance abuse, suicidal tendencies, other severe psychiatric disorders, cognitive disability or people who had insufficient knowledge of English were excluded. E-Compared trial[15] participants were invited to participate in the study if they: (a) provided written consent to be involved in the qualitative interviews when they enrolled on the trial (total number of participants, n=101); (b) were randomised to the b-CBT arm (n=49); and (c) had completed at least one computerised module and face-to-face session (n=42). We purposively selected individuals who represented the sample of participants in the treatment arm, in relation to their sex, age, and recruitment site.[16] Altogether, 26 out of 42 people were invited to take part in the qualitative study, with 19 re-consenting to participate. The remaining seven participants were unable to take part in the study, because they could not find an appropriate time to attend an interview (n=2), did not respond to a formal invitation to participate in the study (n=4), or did not meet the eligibility criteria $(n=1^{ii})$.

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Procedure

> E-compared participants were invited to take part in face-to-face individual semi-structured qualitative interviews, at least 2 weeks after they completed their course of therapy on the trial. This was to provide participants with enough time to reflect on their experience of the b-CBT intervention. Potential participants were invited to take part in one-to-one semi-structured interviews about their experience of b-CBT, and were emailed a patient information sheet (PIS) following their initial correspondence with the research team. Participants were provided with at least 48 hours to read and consolidate the information, before they were followed up and booked in for a qualitative interview at an acceptable time and place. Written consent for their participation was sought again prior to starting their interviews and were reminded of their right to withdraw at any time and without giving a reason. Data collection took place until saturation was reached.[16] The study adopted Corbin and Strauss's definition of saturation, which is described as the point where further data collection becomes 'counter-productive', and where 'new' themes do not add anything to the overall narrative of the story.[16] Saturation was monitored through writing memos after each interview, in which information on both key and novel emerging themes from the interview were recorded.[16]

166 The project was approved by the Health Research Authority's Ethics Committee on 17th April
 167 2015 (REC reference: 15/LO/0511) and the London School of Hygiene and Tropical Medicine
 168 Research Ethics Committee on 9th June 2015 (Ethics Ref: 9409).

9 169 Measures

Self-reported WA and symptoms of depression, collected on the E-Compared trial[15] were
 reported to further describe participant characteristics (in addition to sociodemographic data)
 and to provide insights on WA and the level of depression experienced by the participants on
 the study. Self-reported WA was assessed through the Working Alliance Inventory Short Form

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- Client (WAI-SF-C).[17] Scores for the 12 items on WAI-SF-C range between 12- 60. Scores
were divided into 3 groups to produce a low-range (12-28), medium-range (29-44), and highrange (45-60) to indicate the level of WA reported by each participant. Higher scores indicate
better WA. Self-reported depression was assessed through the Patient Health Questionnaire-9
(PHQ-9).[18] Scores for the 9 items on the PHQ-9 range between 0-27. Higher scores indicate
more severe symptoms. Data was collected during the trial's three months follow-up
assessments.[15]

181 Guiding framework

Our study adopted Edward Bordin's [8,9] theory of WA to explore in the context of b-CBT for three reasons. The first relates to the generalisable nature of the theory. While the concept of the alliance stemmed from psychodynamic theory in 1912, it has since been incorporated in various therapeutic approaches, leading to heterogeneity in the way the concept is defined.[11] In 1979, Bordin[8,9] attempted to unify the way the alliance is defined, by proposing a pan-theoretical conceptualisation[8] that drew on the key features of all therapeutic approaches.[11] Second, Bordin's [8,9] theory is operationalised as task focused, [11] and therefore offers a suitable fit for task-orientated psychological approaches such as CBT.[19] Third, the theory is open to adaptation. Bordin[8,9] suggested that while a pan-theoretical approach allowed the basic measurement of the bond, goals and task to produce beneficial therapeutic change, he also suggested that the ideal alliance profile is likely to be different across therapeutic approaches and interventions.[8,9,11]

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195 Data collection

Data collection took place between October 2016 and July 2017 across four primary care
 mental health services in the UK. Qualitative interviews were adopted to enable a detailed
 examination of the participant's personal experiences and perspectives of WA within the

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context of their experience of receiving b-CBT. The study predominately included a deductive approach to exploring WA in b-CBT based on Bordin's[8,9] theoretical framework, while remaining open to novel or unexpected inductive new findings. On average, participant interviews lasted around 47 minutes. Interviews were conducted in a confidential setting within a university campus or the health service which the participant was recruited from. All interviews were audio-recorded using an Olympus digital voice recorder WS-852 and transcribed to produce orthographic verbal verbatim. AD (female) conducted the qualitative interviews, was a PhD Candidate with experience of conducting and analysing qualitative interviews. Semi-structured interviews with a conversational technique was used to achieve a balance between the need for consistency of questioning across participants, and the ability to explore topics that are important to the participant. During interviews there was also scope to allow topics covered to evolve iteratively based on the emerging data.[16,23] The development of an interview topic guide was supported by patient involvement input and guided by the WA theory[8,9]. The initial topic guide was used to suggest topics of discussion, and not as a definitive framework to limit conversations. As the data collection progressed, the topic guides evolved iteratively based on emerging themes. Subsequent interviews were therefore influenced by interviews that previously took place, providing opportunities to validate and refute interpretations.[16]

218 Data analysis

A preliminary data analysis took place alongside early interviews, allowing subsequent interviews to progress iteratively.[16] Memos were written after each interview, to aid the preliminary analysis and iterative adaptation of the topic guide and to propose possible relationships between codes. Thematic analysis was adopted due to the theoretical flexibility,

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as well as the 'thick descriptions' afforded by the approach.[24] The data analysis incorporated a constant comparative method from grounded theory, to enable the analyst to search for new theoretical models that are grounded in empirical data, and to enhance the trustworthiness of data.[16]

The lead analyst (AD) commenced the data analysis by reading through the transcripts, while listening to the audio recording and reading the corresponding memos. The analyst then actively re-read the data, searching for meaning, and noted down initial concepts. Data was coded line-by-line. Codes were generated by searching for interesting features across the entire dataset and collating data relevant to each code segments. The emerging codes were clustered into categories and labelled thematically. Once the data was initially coded and collated, the analyst commenced searching for themes that were compatible with Bordin's [8,9] WA theory and patient involvement input, while also searching for novel alliance concepts. Themes were located at a latent level, to delve beyond the semantic content of the data, to identify and examine underlying ideas, assumptions, conceptualisation and ideologies that theorise semantic content of the data.[24] The initial codes were gradually merged into broader categories through comparison across transcripts, to identify overarching themes. The themes were then reviewed to ensure that the codes cohere together meaningfully, while maintaining a clear and identifiable distinction with no overlap between the themes. Finally, the themes were reviewed to consider their relationship to the overall thematic map. Once a thematic 'map' was identified, the findings were developed into a conceptual framework of WA in b-CBT.[24] Two other members of the research team (CF and DM), who are highly familiar with qualitative methodologies and Bordin's [8,9] WA theory, read through 20% of all transcripts and reviewed all supporting quotes across all phases of the analysis, so that close to half of the transcripts were reviewed. Discrepancies were discussed and reconciled. The final framework was discussed and revised over eight meetings. The entire coding process was performed using the

NVivo 11 data analysis software package. Supporting quotes were anonymised to ensure thatthat participants and their therapist could not be identified.

To ensure the final conceptual framework truly reflected WA, a 'therapeutic process', was not confounded with early manifestations of 'treatment outcomes' we defined "therapeutic processes" relevant to WA, and the 'treatment outcomes' associated with CBT.[17] 'Therapeutic processes' was defined as "actions, experiences, and relatedness of the client and the therapist in therapy sessions...".[25] We a-priori extended the use of the term 'therapy session' to include face-to-face and digital delivery in the context of blended therapy. Horvath and colleagues [17] noted three ways of defining the outcome in psychotherapy including: (a) the core value attributed to the outcome by the client, (b) the importance of the outcome in the theoretical framework of the therapist, and (c) the utility of the outcome (e.g. the technique) to promote other outcomes that are valued. We defined outcome in relation to definitions b and c to enable a standardised definition that does not vary from client-to-client (i.e., definition a). We a-priori define the outcomes of CBT as the alleviation of distress (b) through helping the client to develop more adaptive cognitions and behaviours (c).[19] The final conceptual framework was reviewed in light of the aforementioned definitions by members of the research team. Themes and sub-themes that were judged to correspond with the definition of 'treatment outcome" were removed. We used the SRQR checklist when writing our report.[26]

267 Patient and public involvement

Patient advisors were enlisted at a pre-research data collection stage to collaboratively examine WA in a digital CBT program without human support. Patient advisors were not involved in the recruitment of participants or of conducting the study. Patient involvement included eleven advisors with experience of mental health service use. Advisors attended two meetings in the summer of 2015. The first meeting consisted of a comprehensive pre-involvement preparation Page 15 of 46

BMJ Open

briefing, to provide advisors with the knowledge and skills that would enable optimal conditions to aid their role.[20] Advisors were also provided with access to a computerised CBT for depression program called Moodbuster (program used on the E-Compared trial),[15] which they were encouraged to test and review in their own time, to provide context for discussion.[20] Advisors voluntarily tested all components of the Moodbuster intervention between meetings. In the second meeting, advisors were split into three small focus group discussion interviews, to facilitate the sharing of personal experiences and enable a higher level of opportunities to participate.[21] Discussions attempted to address three pre-patient involvement objectives, including: (i) is WA, as defined by Bordin[8,9] relevant in the context of a digital program intervention? (ii) What are the intrinsic WA demands between the client and digital provider? and (iii) Can digital delivery offer new ways of building WA, above and beyond Bordin's [8,9] bond, goals and task? The three focus group discussions were audio-recorded using an Olympus digital voice recorder WS-852, transcribed, and analysed to identify thematic patterns and themes. Patient involvement contribution was reported in line with version 2 of the Guidance for Reporting Involvement of Patients and the Public Short Form (GRIPP2-SF).[22] Patient advisors were thanked for their contribution after their involvement and also in the acknowledgements of this paper. The results of the study will be disseminated via a lay summary of the research which will be supplemented with a peer-reviewed publication.

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Patient involvement was instrumental in shaping the focus of the study and in guiding
participant interviews in three different ways: First, patient involvement input suggested that
Bordin's[8,9] WA as a function of enhancing engagement, was both relevant and important in
the context of a digital psychological intervention. Second, the focus of the planned participant
interviews changed from exploring WA within a computerised CBT (c-CBT) intervention only,

to exploring the shared therapist-program format of CBT, as advisors unanimously suggested
that some WA needs (especially bond and elements of support) could not be satisfied without
human facilitation. Third, we set out to extend Bordin's[8,9] WA theory as patient involvement
suggested that the c-CBT program could lead to additional alliance building and maintenance
features.

RESULTS

Description of sample

An exploration of WA in b-CBT was undertaken through 19 qualitative interviews with participants who experienced b-CBT in the treatment arm of the E-Compared trial[15]. Participants were aged between 19-67 years (Mean=34.47 years, SD=14.44 years), largely male (n=13), white British or white other (n=12), and university educated (n=12). All interviews were conducted face-to-face apart from one, which was completed by phone. Saturation appeared to be reached by the 16th interview. Another three interviews were carried out to ensure that the selected saturation cut-off point had been accurately identified and to further validate interpretations. Tables 2-4 show that the main themes were endorsed by 89% -100% of participants, indicating that the selected saturation cut-off point was sufficient.

Table 1.	Sample characteristics	of participants who took	k part in the qualitative interviews (n=1	9)
	oumple onuracionoliou	of purilopunito who tool	r part in the qualitative interviewe (if	ς,

Mean (SD) or Percentage (<i>n</i>)	
34.47 (14.44) range 19- 67 years	
69% (13)	
5% (1)	
11% (2)	
63 % (12)	
21% (4)	

Highest educationa	level completed	
Secondary	r School, equivalent	11% (2
Colleague	equivalent	26% (5
University	degree or higher	63% (12
Ethnicity		
British whi	te or white other	63.1% (12
Black/Afric	an/ Caribbean / Black British	5.3% (1
Asian or A	sian British (Any other Asian)	21% (4
Mixed or N	Iultiple Ethnic Group	5.3% (
Other Session completion		5.3% (
	l course b-CBT	63.2% (12
	e course of b-CBT	36.8% (7
WAI-SF-P*		46.29 (SD=10.21), score range 27-60 (1
High WAI-	SF-P	score range 47-60 (10
Medium V	'AI-SF-P	score range 31-41 (
Low WAI-	SF-P	score range 27 (
No score		(4
PHQ-9**		7.8 (6.87), score range 1-22 (n=1

316 Conceptual framework of WA in b-CBT

A thematic analysis with a constant comparative method[24] revealed multifaceted WA demands which show that the work of building WA in b-CBT involves a symbiotic effort by the therapist and the digital program, to actively engage the client to meaningful therapeutic activities and to promote self-discovery and commitment to the intervention. Such demands can be grouped into four overarching WA themes, (1)'bond', (2)'task', (3)'goals' (in line with

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Bordin's [8,9] WA theory categoriesⁱⁱⁱ) and (4)'heuristics' (a newly emerging theme) (See Fig. 1 for a summary of the main themes and sub-themes).

Theme 1: Bond

The 'bond' is defined as a set of provider competencies that enable a working relationship to be established and maintained with a client. Participants unanimously reported that a human therapist was the most important facilitator for building the bond in a b-CBT context. This was because participants valued qualities of 'humanity', and 'responsiveness' attributed to a human therapist. Through a process in which participants appeared to compare and contrast the strengths of the digital program with a human therapist, most participants questioned the 'meaningfulness' of interacting with a digital platform that was incapable of understanding or responding to a client's needs as demonstrated by the following quote:

"an app is like a machine, it's not personal at all. I think it's good to have some element[s] of talking to a human about this kind of thing because I think you want reassurance as well, which you wouldn't get from an app and if you did it would just be responses built in".

(P8, M, 24 y/o, lower-range Working Alliance Inventory Short Form – Client (WAI-SF-C))

Data from participant interviews revealed three broad therapist attributes considered to be important for the bond building process, namely the mental health providers' ability to; effectively demonstrate their understanding of their client's struggles and needs (sub-theme 1.1); convey that they are genuine in their endeavours towards the client (sub-theme 1.2); and forge a working partnership founded on friendliness, feeling cared for, empathy and trust (sub-theme 1.3) (see Table 2 for sub-theme descriptions and supporting quotes). Some participants

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elaborated on these concepts further to unearth granular insights of what it means to be in the
presence of a human therapist. Visually observing a therapist's non-verbal cues was reported
to be especially important for gauging abstract relational concepts such as empathic
understanding (sub-theme 1.1), and genuineness (sub-theme 1.2). The recognition of positive
non-verbal cues appeared to increase congruence between the therapist and the client (subtheme 1.3) throughout the course of therapy:

"[During telephone therapy] he was like "mm hm, go on...so how do you feel?" I can't see his face. I don't know what he was thinking. I can't feel him. But during face-to-face [sessions] I think when I talk about something I can notice, his or her like facial expression. I know he's listening ...That make[s] me feel like talk[ing] more". (P14, M, 34 y/o, WAI-SF-C score not available^{iv})

 Table 2. Theme 1, bond sub-theme descriptions and supporting quotes

Theme, percentage of sample endorsed	Supporting quotes
(<i>n</i>) and description	
THEME 1: Bond, 89%, (17)	2
1.1 Feeling understood, 74% (14)	P12, M, 23 y/o, high-range WAI-SF-C score:
The therapist's ability to make the client	"My therapist did make a real effort to try and get to know me, try to
feel understood. This requires the therapist	maybe get to know what made me tick and why I was feeling how I
to closely listen to the client, comprehend	did, rather than just assuming this is what you need without taking
what is being said and demonstrate	into account maybe what I as a person, personally needed".
empathic awareness and insight into the	
client's concerns.	
1. 2 Genuineness, 32% (6)	P17, M, 39 y/o, WAI-SF-C* scores not available:
The therapist's efforts to help the client,	"I never felt we were just going through the sort of motions if you like
that are perceived as genuine and	if there was a list of things to do, well this is what you want to do, it
	seemed more than that"

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 authentic, as opposed to procedural or routine.

 1.3. Partnership, 74% (14)
 P12, M, 23 y/o, high-range WAI-SF-C score:

 The ability of the client and therapist to achieve a working relationship that is akin
 "I feel like she, as I said earlier, took the time to get to know me and ... what I was currently doing, so it did feel like she kind of knew me on an individual level, rather than just being the patient."

 to a friendship. Such a partnership is characterised by trust, feeling liked and feeling cared for.
 on an individual level, rather than just being the patient."

*WAI-SF-C: Working Alliance Inventory Short Form- Client.

360 Theme 2: Goals

Goals' refers to the collaborative work between the therapist, the client and the digital interface, to appropriately identify what the client hopes to achieve through therapy (68% of sample endorsed the 'goals' theme, n=13). While 'goals' emerged as a distinct factor, it also appears to be interrelated with the 'task', thereby playing a fundamental role in framing activity-based tasks and maintaining the client's motivation to work towards creating change.

366 "The goal setting actually was something that I spoke to [the therapist] quite a bit about
367 in the session [...] I was then like "God well what are my goals? [...] what, where am
368 I exactly going?" (P5, M, 22 y/o, higher-range WAI-SF-C score)

370 Theme 3: Task

The 'task' refers to the careful selection and acceptability of the therapeutic activities prescribed to address the client's presenting symptoms ('activity-based task'), and the degree to which the support received by the healthcare provider on these activities is responsive ('responsive support').

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The defining features of 'activity based-task' refers to the client's ability to work on tasks that are; personalised and acceptable for addressing the client's therapy goals (sub-theme 3.1); useful in promoting new learning, insights and reflection (sub-theme 3.2) and are complimentary across both modes of delivery (sub-theme 3.3). The defining features of 'responsive support' relate to the provider's (largely referring to the therapist's role) ability to appropriately respond to a range of clients' expressed and unexpressed need to; maintain accountability (sub-theme 3.4); provide activity-based guidance (sub-theme 3.5); and have a safe-space for clients to express their feelings and emotions (sub-theme 3.6) (see Table 3 for sub-theme descriptions, and supporting quotes).

Table 3. Theme 2, task sub-theme descriptions and supporting quotes

Theme, percentage of sample endorsed (<i>n</i>)	Supporting quotes
and description	
THEME 3: Task 100%, (19)	\sim
Activity-Based Task, 100% (19)	
3.1. Personalisation, 95% (18)	P12, M, 23 y/o, high-range WAI-SF-C Score:
The level at which a client is able to tailor the	"I think it's a bit more personalised, because I would say
therapeutic task to their individual needs. A non-	whilst the E-Compared is good, it is still, it is to an extent
personalised digital intervention was reported to	generic, because it can't kind of know every single person
negatively impact engagement. The therapist in	that's watching the video, so whereas the therapists can ki
blended-therapy can play an important role in	of get an idea of you, your story, your journey, what's mayl
making a generic intervention (i.e. computerised	led you to kind of this maybe relapse, or for you to be feelin
CBT) as more personalised.	the way you are, and you can't maybe get that from a
	computerWhereas if I'm hearing it from the person, I'm
	going to take a bit more notice, but then if I'm just hearing i
	from the computer, where it will say that to everyone
	watching the video"

3.2. Usefulness, 95% (18)

P4, F, 18 y/o, medium-range WAI-S-C score:

60

1 2 3

A useful task was defined as one that promotes new learning, reflection and is effective in creating desired change in the client's life.

"But like the modules themselves, feelings-wise they were often quite helpful for clarifying stuff. Like I usually came out the other end feeling better or more kind of composed...it would kind of shape how I was seeing things. So like if I, you know learned about thought distortions, I'd kind of go in with that knowledge and be able to kind of talk about it..."

3.3. Complementary, 84% (16)

The ability to experience complementary tasks in face-to-face therapy and on the digital platform as continuous and cohesive, as opposed to stilted and disjoint. Knowing what to expect from the respective components of blended therapy was reported to help the client optimise the benefits sought from different components of therapy. "I was finding it really hard to leave the house so that whole thought of going to therapy was quite difficult in the very beginning, so it did take me a couple of sessions to really start talking to [therapist] and opening up but because I had this online support I found it easier to open up to [therapist] so maybe instead of you know, two sessions it would have taken four or five."

P16, F, 35 y/o, medium working alliance:

Responsive support Task, 100% (19)

3.4. Accountability, 79% (15)

The availability of a figure of authority that the client can (positively) feel responsible towards, as a means of garnering motivation to work on therapeutic activities. For the process of accountability to positively impact the client's motivation, a therapist is required to demonstrate their knowledge of the client's progress and provide feedback accordingly.

3.5. Guidance, 89% (17)

The provision of guidance and reassurance on the therapeutic tasks by a therapist. The therapist's intuition, expertise, interpretation and foresight is especially considered as helpful in P19, M, 59 y/o, medium-range WAI-S-C score: "Oh right, OK. Well, to me, I saw it like homework, you've got to get it done otherwise you get into trouble, not that I would have got in trouble, but do you know what I mean, you're sort of motivated that way. And there is the other, the embarrassment of going in and saying 'oh yeah, I didn't do the modules' and then you feel really about that big and you know, someone's trying to help you and you haven't bothered to do your bit kind of thing. So that was a motivation in itself."

P10, M, 45 y/o, high-range WAI-SF-C score:

"When you speak to your therapist, obviously she's had a lot of different scenarios with a lot of different people, she's got the experience and the know-how, and then obviously how I'm looking at it thinking the module's really working like this, she

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2			
3		addressing salient issues that would not have	then says, "That's really brilliant, but to then add onto that and
4 5		otherwise been communicated by the client.	to support you, how about if you think about that?."
6			
7			
8			
9 10		3.6. Expression of feelings 100% (19)	P14, M, 34 y/o, WAI-SF-C score unavailable:
11		S.O. Expression of reenings 100% (19)	
12		The client's expressed need to speak to another	"I think it's nice to have someone to talk to. It's kind of, I think
13 14		human being, in order to communicate issues	it's important for me to express my feelings like in a private
15 16		that are pertinent to their treatment journey. In	situation. Because sometimes I have, kind of I live with my
17		order for the client to optimally benefit, clients	partner but, you know, some[times], you can't talk to her."
18 19		require the therapist to dedicate a sufficient	
20 21		amount of time for the activity. The amount of	
22		time required by each person appears to vary in	
23 24		relation to pre-therapy expectations and	
25 26		symptom severity.	
27		WAI-SF-C: Working Alliance Inventory Short Form	n-Client
28		with of o. working fundree inventory chort for	
29 30	205		
31	385		
32 33	386	The majority of participants noted the imp	portance of experiencing the therapeutic activity as
34 35	387	complementary across modes of delivery	(sub-theme 3.3). Some participants elaborated that
36		1 5 5	
37 38	388	an initial step to achieving an effective sy	mbiotic delivery was to provide the client with an
39 40	389	understanding of how the therapist and digi	ital delivery contributed towards their treatment both
40 41			
42	390	distinctively and collectively.	
43			
44 45	391		
45 46	202	Our findings also suggested that the uniqui	ty of a CDT approach to positively impact the alient
47	392	Our findings also suggested that the ubiquit	ty of c-CBT appeared to positively impact the client-
48	393	therapist WA, through increased opportuni	ties to reinforce what was learned through the digital
49 50			
51	394	platform, with a therapist, and vice-versa,	for instance:
52			
53 54	395	"Well I think it gave you something	g to do over and above the face-to-face having the
54 55		" en 1 man a gave you sometime	5 to as over and above the face to-face having the
56	396	modules to go through, it reinforce	s what you're talking about face-to-face and makes
57 58		-	
58 59			

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it easier to understand. It's, that repetition thing isn't it where you learn by repetition basically and that's how I saw it working."

(P17, M, 39 y/o, WAI-SF-C score not available)

401 Theme 4: Heuristics

The final alliance building theme identified is, 'heuristics', which refers to the process of predominantly using technology to promote active engagement, self-discovery and autonomous problem solving in b-CBT. This category is a novel component to Bordin's[8,9] theory. Features that enable 'heuristics' include ubiquitous digital technologies that; increase access and immediacy to the therapeutic task (sub-theme 4.1), appropriately respond to the client's input (sub-theme 4.2), are easy to use (sub-theme 4.3) have aesthetic appeal (sub-theme 4.4) and promotes self-directed therapy (sub-theme 4.5) (see Table 4 for sub-theme descriptions, and supporting quotes).

While therapist competencies emerged as the most important facilitator for building the alliance, almost all participants expressed that blended psychotherapy was superior to face-to-face therapy alone. Some participants elaborated that their ability to access the intervention at any time or place of convenience (sub-themes 4.1) further bolstered their engagement to therapeutic activities (theme 2). Participants who reported a high technological affinity suggested that the appearance (sub-theme 4.4) and ease of use (sub-theme 4.3) of the interface impacted their perceptions of the digital program's credibility and therefore, their desire to engage in treatment activities.

Almost all participants reported that the digital program provided them with the tools to initiate Almost all participants reported that the digital program provided them with the tools to initiate treatment independently (sub-theme 4.5), with some participants noting that they continued to use the digital program as a means of maintaining therapeutic gains once their therapy course

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421 had ended. Here, autonomous completion of the therapeutic task was described as a secure-422 base that allowed clients to progressively explore self-directed therapy:

"it kind of reminds me of Winnicott and the Secure Base in Attachment theory in psychology, that you know, children become securely attached if they have a secure base in terms of the home and the parents that they can come back to, so they can go off and explore the world confidently in the knowledge that they can come back to security, and that, that helps them to develop - and it's kind of like that, I feel, with having that Moodbuster resource [digital program] there, that you can keep coming back to it ... there is a lot in there and you can keep going back and it's a sort of source of strength really".

431 (P10, M, 51 y/o, higher-range WAI-SF-C score)

Participants suggested that the blended approach prepared the client to engage in autonomousself-directed therapy, through a process of supervised autonomy.

Theme, percentage of sample endorsed (<i>n</i>) and	Supporting quotes
description	
THEME 4: Heuristics, 100% (19)	
4.1. Accessibility, 95% (18)	P10, M, 45 y/o, high-range WAI-SF-C score:
The ability of a client to access the digital	"Being on your own you know, in your own time and in
intervention at a time and place of convenience.	your own safe place, your blanket, whatever you call it just
Higher accessibility provides opportunities for the	allowed me personally just to open up and look at it, and
client to review and reflect on what has been	then going from the start of the process to the end, \ldots
learned at a deeper level.	thinking positively, looking at your behaviours, looking at
	adding little things in and then the exercise at the end,
	rewarding yourself for just achieving things what I felt at
	the time were trivial made everything different."

4.2. Interactivity, 63% (12) An interactive digital program that is able to react to the clients input, to produce feedback. Interactive activities were perceived as more enjoyable, and promoted a degree of accountability.

4.3. Ease of use, 63% (12)

The ease of use of the digital interface is described as a well-functioning, intuitive, digital interface which enables optimal access to the therapeutic task.

4.4. Aesthetic appeal, 21% (4)

The appearance or appeal of the digital interface is a factor that clients use to judge the credibility of the digital intervention and which could impact their engagement to the therapeutic task.

P6, M, 22 y/o, high working alliance:

"One thing immediately comes to mind, it has to be a bit more interactive I think. The client shall we say, as well I feel should be given more feedback, the results, you know when you're scoring yourself on those, what that's about you know, how do they interpret that score, when you're putting your mood in on the smartphone, what's that about you know, who's looking at that, who's interpreting that".

P2, F, 23 y/o, high-range WAI-SF-C score:

"It was really nice, I thought it was really, well very well presented I would say, and everything was just there, like for easy viewing, so you didn't have to like go through like folders or like go deeper into the website, like it was just there, and you know, I could just easily click on what I needed to do and just follow the instructions set out on the exercises."

P13, M, 24 y/o, medium-range WAI-SF-C score: "Yeah, and actually it became quite a bit of work just keeping up with the calendar, sort of, I found it a bit clunky, but then I worked in I.T for sixteen years...".

4.5. Self-directed, 79% (15)

The process of taking responsibility for one's own behaviour and well-being, appears to instil clients with a sense of independence and control.

"Other times it was good kind of to do a time and also independence, kind of learning to do stuff without a therapist there...I quite liked that I could, I don't know for me because it, I suppose it ties back into the independence thing, but because I was doing it on my own

I almost proved I could do it on my own...because I feel like sometimes with a therapist you almost become like

but then I worked in I.T for sixteen years...". P3, F, 19 y/o, medium-range WAI-SF-C score:

 dependent on them or, it's like being taught something, when you're like dependent on the teacher."

DISCUSSION

437 Statement of principal findings

The results of the study present a preliminary conceptual framework of WA in b-CBT. It can be seen that Bordin's [8,9] 'bond', 'goals' and 'task' appear to be relevant in blended formats of CBT, however the priorities of WA demands have shifted to meet the client needs within a blended format. Moreover, an entirely new category 'heuristics', emerged as a novel means of promoting a new level of WA through a process of self-directed discovery and autonomous problem solving. Participants also explained that different modes of delivery by the therapist (e.g. client-provider bond, responsive support) and the digital program (e.g., upholding goals, task and promoting heuristics) were useful for meeting different WA demands.

37 446 **Stre**

Strengths and limitations of the study

Based on our search, this study is the first to provide an account of WA in b-CBT, and insights on how different treatment roles within a blended format of therapy, are used to meet different WA demands. This is especially important given that, digital technologies are increasingly being used to treat mental illness, [4] and that WA plays an important role in promoting positive therapeutic change.[11] The design of our study had two key strengths. First, we used the most comprehensive and commonly used theory of the 'alliance' to approach our study.[27] Second, involving patient involvement enabled the project to be grounded on the needs and interests of people who have experienced mental illness and service use, thereby enhancing the application of the findings.[20] There are also several limitations to be noted. First, our sample was limited to 19 individuals with a primary diagnosis of mild-to-moderate depression who largely reported

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> moderate to high WA, thereby restricting the generalisability of our findings to other clinical presentations. Exposure to only one type of digital program, may have influenced participant's experience of WA. For instance, a computerised platform that doesn't work adequately might generate more data on the importance of 'ease of use', than one that does. Some of these issues were pre-empted ahead of the study. Efforts were made to broaden the reach of the conceptual framework in two ways. First, emerging participant data was guided by key literature on the alliance and patient involvement input. Second, our qualitative data analysis avoided the use of surface level themes, such as specific technological design. Instead, latent thematic analysis was used to unearth underlying psychological processes.[24]

467 Strengths and weaknesses in relation to other studies, discussing important differences in 468 results

Participants fed back that, while it was essential for therapeutic activities to be complimentary between modes of delivery, they also suggested that modes of delivery can uniquely meet different WA needs. For instance, participant unanimously fed back that the human therapist played an essential role in establishing the 'bond'. The role of the therapist in supporting digital interventions is well documented in the literature.[5] A recent study evaluating the relationship between the client, the human provider and their c-CBT program, found that participants rated their overall treatment approach higher when they experienced c-CBT that was supported by a human provider compared to c-CBT that was unsupported.[6] When attempts were made to unpack the importance of the therapist's role, participants suggested that the therapist's physical presence facilitated the therapist's propensity to convey important features of the bond (sub-themes 1.1-1.3) through verbal and non-verbal communication. This aligns with early psychotherapy research by Karl Rogers [28], who proposed that a therapist's ability to display active listening (empathic understanding, unconditional positive regard, and congruent

Page 29 of 46

BMJ Open

behaviour) was important for positively changing the impressions of the client's perceived negative experiences. Neuroscientific research evaluating the impact of active listening, suggested that the participant's recognition of active listening behaviour in another, can positively change the appraisal of an emotional episode and increased positive impressions of the active-listener.[29] These findings appear to be unique to human-to-human interactions. One study assessing the therapeutic alliance in a digital mental health mobile application for psychosis found that the anthropomorphizing of digital devices was not accepted by clients or mental health clinicians.[30] Given that little gains have been made to effectively deploy emotional artificial intelligence, a tool that is required for the effective biomimicry of humanbeings in the digital space, [31] the exclusion or non-effective deployment of a human provider in digital psychological interventions may therefore compromise the quality of WA.

On the other hand, participants reported that while the therapist was essential for the effective delivery of psychotherapy, blended delivery appears to be superior to therapist delivery alone. Almost all participants reported WA benefits, in form of engagement, to digital delivery (i.e. 'heuristics'), through desired opportunities to engage in self-directed therapy. Our findings are echoed in the digital mental health user-experience and the alliance literature, which indicate that digital psychotherapy can enhance the client's perceived control, autonomy and feelings of empowerment, when sufficient human support is provided.[30,32] Our findings suggest that digital delivery within a b-CBT format cannot be disentangled from WA. For instance, a digital program that was perceived as non-interactive appeared to cause ruptures in engagement with 'activity-based task'. Given that digital delivery appears to have a significant impact on engagement with 'activity-based task', we argue that the inclusion of features that uphold existing alliance structures should therefore be accounted for in the WA framework. Our findings align with Bordin's [8,9] conceptualisation of WA, who proposed that the therapeutic tool cannot be disentangled from the means in which the alliance is built. This therefore

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suggests that the client-program WA can have an impact on the client-therapist WA, and viceversa, contrary to research findings that suggest that WA contributions are independent and additive.[6]

The 'task' appears to play a central role in b-CBT, as initially theorised by Bordin[8,9]. Our findings appear to address Bordin's[9] call to distinguish between the task that is in service of 'building WA' (responsive support) and the tasks in the service of 'change' (activity based-task). While many of the 'task' sub-themes appear to be novel to Bordin's [8,9] WA, with the exception of complementary tasks (sub-theme 3.3), all other 'task' sub-themes, are in fact implicit his broad conceptualisation. The integration of technology in psychotherapy has prompted a re-evaluation of the demands placed on WA by a blended psychotherapeutic format. For example, the concept of accountability is implicit and forms one of many appendages associated with the human therapist's role in building and maintaining WA. However, this concept has been propelled to the forefront as an essential ingredient for maintaining the alliance in b-CBT, in line with David Mohr and colleagues' 'supportive accountability' model for e-health.[33]

While 'bond', 'task' and 'heuristic' emerged as distinct themes, the 'goals' appears to be especially interlinked to the 'task'. The data from the qualitative interviews suggest that 'goals' was grounded in 'goals-setting activities'. This however diverges from Bordin's[8,9] description of the goals, which appears to move further, to address the therapist's efforts to unearth the core struggles that have bought the client to psychotherapy, in great detail[9]. One possible reason for our findings may be explained by the time-lag between the assessment and the first therapy session, which may have led participants to only focus on their course of b-CBT and not the proceeding assessment where more in-depth explorations of the client's struggles and goals generally take place. On the other hand, our study is not the first to question

Page 31 of 46

BMJ Open

the operational distinctiveness of the 'goals' and the 'task'. The psychometric evaluation of the Working Alliance Inventory, based on Bordin's [8,9] WA suggested that concepts were highly interrelated,[17] while a more recent psychometric evaluation found that concepts did not emerge as distinct factors.[34]

Meaning of the study: possible explanations and implications for clinicians and policymakers

Our findings address, at least in part, three of 10 clinical and research priorities of digital technology in mental health care identified by people with lived experience of mentally illness, carers and health and social care practitioners (See Box 1).[7] WA, a common element of psychotherapy appears to be both relevant and important in b-CBT. Human delivery appears to be central to the maintenance of empathy, gestures and non-verbal cues in which the therapist role in b-CBT may focus on establishing the bond, and developing and maintaining the client's engagement through responsive support (Q8). Participants noted that both modes of delivery collaboratively contributed to the building of the alliance through distinctive pathways. While human support is perceived as 'responsive' and 'meaningful', digital delivery appears to promote autonomy and self-directed discovery (e.g. accessibility and self-directed therapy) and plays an important role in maintaining WA across 'goal' and 'task' activities (e.g. ease of use, interactivity of digital program and aesthetic appeal). Our finding appear to indicate that removing human support, seen as essential for the 'bond' and 'responsive support', may increase the risk of therapeutic ruptures and disengagement with psychological interventions delivered through a blended format (Q1 and Q3). These findings can be used to promote WA in technological design and clinical practice, thereby promoting engagement to b-CBT interventions, and the effective deployment of therapist and digital support resources.

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Box 1. Top ten research priorities for digital technology in mental health care, identified by the Priority Setting Partnerships [7].

Q1. What are the benefits and risks of delivering mental health care through technology instead of face-to-face and what impact does the removal of face-to-face human interaction have?

Q3. How can treatment outcomes be maximised by combining existing treatment options (medication, psychological therapies, etc.) with digital mental health interventions

Q8. Can the common elements of therapy (eg, empathy, gestures, non-verbal cues) that come from personto-person interactions be maintained with digital technology interventions?

556 Unanswered questions and future research

We propose three directions for future research. First, while our findings outline WA demands in b-CBT, it is unknown if fulfilling such demands will lead to positive clinical change. Future research should aim to investigate if self-reported WA as defined by our conceptual framework, predicts therapy outcome. Second, WA should be further explored across different computerised programs and other digital technologies (e.g. virtual experiences, gamification and text-based intervention) intended for use within a blended format, especially in relation to understanding the demands of different digital technologies in shaping 'heuristics'. Third, our findings can be used to inform the design of BIT theories, as a means of enhancing engagement and adherence to the digital components of blended interventions for mental health.

567 Word count: 5716

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685 FOOTNOTES

686 Author contribution

Asmae Doukani (AD) developed the concept of the work. Patient involvement. shaped the focus of the research. AD led all aspects of patient involvement. Arlinda-Cerga Pashoja (ACP) and Shumaila Usmani assisted with the SUI focus groups. The design and analysis of the SUI focus groups was contributed to by Sarah Smith (SS), Jesus Montero-Marin (JMM), and Caroline free (CF) and Ricardo Araya (AR). AD, CF, SS significantly contributed to the design of the qualitative participant interview and Nicki Thorogood provided guidance in respect to the methodology. AD led all aspects of data collection, analysis and interpretation. CF and Daniel Michaelson (DM) analysed a portion of the data independently. The iterative development of the conceptual framework was overseen by DM and Ritsuko Kakuma (RK), and contributed to by CF, RA, SS and ACP. AD prepared all iterations of the manuscript, with significant contributions from RK, CF, DM, RA, JMM, ACP and SS.

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facilitate and transcribe the patient involvement focus group interviews.

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706 Conflict of interest: All authors have completed the ICMJE uniform disclosure form at
 707 www.icmje.org/coi_disclosure.pdf and declare: no support from any organisation for the
 708 submitted work; no financial relationships with any organisations that might have an interest

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in the submitted work in the previous three years; no other relationships or activities that couldappear to have influenced the submitted work.

Ethical approval: The project was approved by the Health Research Authority's Ethics
Committee on 17th April 2015 (REC reference: 15/LO/0511) and the London School of
Hygiene and Tropical Medicine Research Ethics Committee on 9th June 2015 (Ethics Ref:
9409).

Transparency declaration: The lead author (AD) affirms that this manuscript is an honest,
accurate, and transparent account of the study being reported; that no important aspects of the
study have been omitted; and that any discrepancies from the study as planned (and, if relevant,

- 718 registered) have been explained.
- **Data sharing statement:** Data available upon reasonable request.

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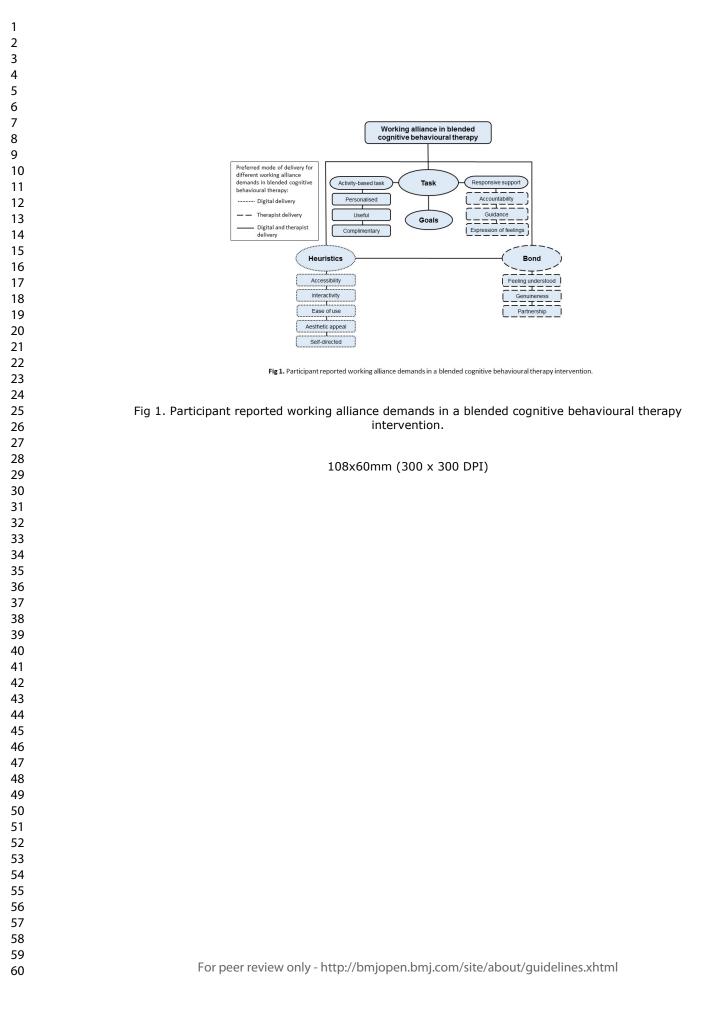
ⁱ The use of the 'alliance' as a singular, broadly refers to the client-therapist alliance, and not to a specific variation (e.g. therapeutic alliance, working alliance, helping alliance etc.,) which while at times used interchangeably, have distinct theoretical underpinnings.

ⁱⁱ A participant who was allocated to the treatment as usual group was erroneously put forward as a suitable b-CBT candidate. This case was discovered during the interview, and corroborated with the E-compared trial manager after the interview. Data for this participant was not analysed.

ⁱⁱⁱ The aim of the study was to explore the relevance of the working alliance and to adapt the theory for the context of a b-CBT intervention. During the data analysis phase, it was decided that emerging data that fitted with Bordin's[8,9] conceptualisation, would be labelled according to existing categories (bond, goal, task). However, while the labels broadly fit with Bordin's[8,9] key categories, these labels are specific to b-CBT WA demands.

^{iv} WAI-SF-C scores are unavailable for participants who did not complete their online 3 month follow-up assessments on the E-Compared Trial.

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COREQ (COnsolidated criteria for REporting Qualitative research) Checklist

COREQ	(COnsolid	ated criteria for REporting Qualitative research) Checklist	
		d in reports of qualitative research. You must report the page number in you	-
where you consider each of tl accordingly before submitting		d in this checklist. If you have not included this information, either revise you. م.	ir manuscript
Торіс	Item No.	Guide Questions/Description	Reported on
Domain 1: Research team			Page No.
and reflexivity			
Personal characteristics			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	
Occupation	3	What was their occupation at the time of the study?	
Gender	4	Was the researcher male or female?	
Experience and training	5	What experience or training did the researcher have?	
Relationship with			
participants			
Relationship established	6	Was a relationship established prior to study commencement?	
Participant knowledge of	7	What did the participants know about the researcher? e.g. personal	
the interviewer		goals, reasons for doing the research	
Interviewer characteristics	8	What characteristics were reported about the inter viewer/facilitator?	
		e.g. Bias, assumptions, reasons and interests in the research topic	
Domain 2: Study design			
Theoretical framework			
Methodological orientation	9	What methodological orientation was stated to underpin the study? e.g.	
and Theory		grounded theory, discourse analysis, ethnography, phenomenology,	
		content analysis	
Participant selection	1		
Sampling	10	How were participants selected? e.g. purposive, convenience, consecutive, snowball	
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, email	
Sample size	12	How many participants were in the study?	
Non-participation	13	How many people refused to participate or dropped out? Reasons?	
Setting			
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	
Presence of non- participants	15	Was anyone else present besides the participants and researchers?	
Description of sample	16	What are the important characteristics of the sample? e.g. demographic data, date	
Data collection	I		
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?	
Repeat interviews	18	Were repeat inter views carried out? If yes, how many?	
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	
Field notes	20	Were field notes made during and/or after the inter view or focus group?	
Duration	21	What was the duration of the inter views or focus group?	
Data saturation	22	Was data saturation discussed?	
Transcripts returned	23	Were transcripts returned to participants for comment and/or	

Торіс	Item No.	Guide Questions/Description	Reported on Page No.
		correction?	
Domain 3: analysis and			
findings			
Data analysis			
Number of data coders	24	How many data coders coded the data?	
Description of the coding	25	Did authors provide a description of the coding tree?	
tree			
Derivation of themes	26	Were themes identified in advance or derived from the data?	
Software	27	What software, if applicable, was used to manage the data?	
Participant checking	28	Did participants provide feedback on the findings?	
Reporting			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings?	
		Was each quotation identified? e.g. participant number	
Data and findings consistent	30	Was there consistency between the data presented and the findings?	
Clarity of major themes	31	Were major themes clearly presented in the findings?	
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	

Developed from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. International Journal for Quality in Health Care. 2007. Volume 19, Number 6: pp. 349 – 357

Once you have completed this checklist, please save a copy and upload it as part of your submission. DO NOT include this checklist as part of the main manuscript document. It must be uploaded as a separate file.

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Reporting checklist for qualitative study.

Based on the SRQR guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SRQRreporting guidelines, and cite them as:

O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. Standards for reporting qualitative research: a synthesis of recommendations. Acad Med. 2014;89(9):1245-1251.

28 29				Page
30			Reporting Item	Number
1 2 3	Title			
34 35 36 37 38 39 40 41 42	Abstract	<u>#1</u>	Concise description of the nature and topic of the study identifying the study as qualitative or indicating the approach (e.g. ethnography, grounded theory) or data collection methods (e.g. interview, focus group) is recommended	3
13 14 15 16 17 18 19 50	ADSITACI	<u>#2</u>	Summary of the key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results and conclusions	3-4
51 52 53	Introduction			
54 55 56 57 58	Problem formulation	<u>#3</u>	Description and signifcance of the problem / phenomenon studied: review of relevant theory and empirical work; problem statement	6-7
59 50	For pe	er review	only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	

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1 2 3 4 5	Purpose or research question	<u>#4</u>	Purpose of the study and specific objectives or questions	6-7
	Methods			
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27 28 29 30 31 32 33 34 35 36 37	Researcher characteristics and reflexivity	<u>#6</u>	Researchers' characteristics that may influence the research, including personal attributes, qualifications / experience, relationship with participants, assumptions and / or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results and / or transferability	12
38 39	Context	<u>#7</u>	Setting / site and salient contextual factors; rationale	12-13
40 41 42 43 44 45 46	Sampling strategy	<u>#8</u>	How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g. sampling saturation); rationale	8
47 48 49 50 51 52 53	Ethical issues pertaining to human subjects	<u>#9</u>	Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues	9 0
54 55 56 57 58	Data collection methods	<u>#10</u>	Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative	12-13
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			BMJ Open	Page 46 of 46
1 2 3 4			process, triangulation of sources / methods, and modification of procedures in response to evolving study findings; rationale	BMJ Open: first published 8-7, 12- 13
5 6 7 8 9 10 11	Data collection instruments and technologies	<u>#11</u>	Description of instruments (e.g. interview guides, questionnaires) and devices (e.g. audio recorders) used for data collection; if / how the instruments(s) changed over the course of the study	as
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17 18 19 20 21 22 23 24 25	Data processing	<u>#13</u>	Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymisation / deidentification of excerpts	10.1136/bmjopen-2019-036299 on 23 Septem Ens 15 15 15 15 13-1 13-1
25 26 27 28 29 30 31	Data analysis	<u>#14</u>	Process by which inferences, themes, etc. were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale	iber 2020. Download reignement Superiei 12-15 12-15
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3 4 5	Limitations	<u>#19</u>	Trustworthiness and limitations of findings	26-31
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13 14 15 16	Funding	<u>#21</u>	Sources of funding and other support; role of funders in data collection, interpretation and reporting	39
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Toward a conceptual framework of the working alliance in a blended low-intensity cognitive behavioural therapy intervention for depression in primary mental health care: A qualitative study

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Primary Subject Heading :	Mental health
Secondary Subject Heading:	Health services research
Keywords:	Telemedicine < BIOTECHNOLOGY & BIOINFORMATICS, MENTAL HEALTH, Depression & mood disorders < PSYCHIATRY

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1	Toward a conceptual framework of the working alliance in a blended low-intensity cognitive
2	behavioural therapy intervention for depression in primary mental health care: A qualitative
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4	
5	Corresponding author
6	Asmae Doukani, Research Fellow
7	Faculty of Epidemiology and Population Health, London School of Hygiene and Tropical
8	Medicine, Keppel Street, London, WC1E 7HT, United Kingdom.
9	Email: <u>Asmae.Doukani@lshtm.ac.uk</u>
10	Telephone: +44(0)207 927 2462
11	
12	Co-authors
12 13	Co-authors Caroline Free, Professor in Primary Care and Epidemiology
13	Caroline Free, Professor in Primary Care and Epidemiology
13 14	Caroline Free, Professor in Primary Care and Epidemiology Faculty of Epidemiology and Population Health, London School of Hygiene and Tropical
13 14 15	Caroline Free, Professor in Primary Care and Epidemiology Faculty of Epidemiology and Population Health, London School of Hygiene and Tropical
13 14 15 16	Caroline Free, Professor in Primary Care and Epidemiology Faculty of Epidemiology and Population Health, London School of Hygiene and Tropical Medicine Keppel Street, London, United Kingdom (Caroline.Free@lshtm.ac.uk)
13 14 15 16 17	Caroline Free, Professor in Primary Care and Epidemiology Faculty of Epidemiology and Population Health, London School of Hygiene and Tropical Medicine Keppel Street, London, United Kingdom (Caroline.Free@lshtm.ac.uk) Daniel Michelson, Senior Lecturer in Clinical Psychology
13 14 15 16 17 18	Caroline Free, Professor in Primary Care and Epidemiology Faculty of Epidemiology and Population Health, London School of Hygiene and Tropical Medicine Keppel Street, London, United Kingdom (Caroline.Free@lshtm.ac.uk) Daniel Michelson, Senior Lecturer in Clinical Psychology School of Psychology, University of Sussex, Pevensey Building, Falmer, Brighton, United

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Health Service and Population Research Department, King's College London, De Crespigny

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58 59	

23	Park, London, SE5 8AF, United Kingdom. (Ricardo.Araya@lshtm.ac.uk)
24	
25	Jesus Montero-Marin, Senior Postdoc Researcher
26	Department of Psychiatry, University of Oxford, Warneford Hospital, OX3 7JX Oxford,
27	United Kingdom (jesus.monteromarin@psych.ox.ac.uk)
28	
29	Sarah Smith, Associate Professor in Psychology
30	Department of Health Services Research and Policy, London School of Hygiene and Tropical
31	Medicine, Keppel Street, London, United Kingdom. (Sarah.Smith@lshtm.ac.uk)
32	
33	Arlinda Cerga Pashoja, Research Fellow
34	Faculty of Epidemiology and Population Health London School of Hygiene and Tropical
35	Medicine, Keppel Street, London, United Kingdom. (Arlinda.Cerga-Pashoja@lshtm.ac.uk)
36	
37	Ritsuko Kakuma, Associate Professor
38	Faculty of Epidemiology and Population Health London School of Hygiene and Tropical
39	Medicine, Keppel Street, London, United Kingdom. (Ritsuko.Kakuma@lshtm.ac.uk)
40	
41	Word count: 6119

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42 Abstract

Objectives: To examine and adapt a conceptual framework of the working alliance (WA) in
the context of a low-intensity blended (psychological wellbeing practitioner (PWP) plus
computerised program) cognitive behavioural therapy intervention (b-CBT) for depression.

46 Design: Patient involvement was enlisted to collaboratively shape the design of the project 47 from the onset, before data collection. In-depth semi-structured interviews were carried out 48 with participants who experienced b-CBT as part of the E-compared trial. A thematic analysis 49 was conducted using a constant comparative method informed by grounded theory.

50 Setting: Recruitment was carried out in four psychological primary care services across the
51 UK.

Participants: Nineteen trial participants with Major Depressive Disorder who completed at
least one computerised programme and face-to-face session with a PWP in the b-CBT arm,
were recruited to the study.

Results: Qualitative interviews that were guided by WA and patient involvement, revealed four themes: (1) A healthcare provider (PWP and programme) with good interpersonal competencies for building a working relationship with the client ('Bond'); (2) collaborative efforts between the client and the provider to appropriately identify what the client hopes to achieve through therapy ('Goals'); (3) the selection of acceptable therapeutic activities that address client goals and the availability of responsive support ('Task'); and (4) the promotion of active engagement and autonomous problem solving ('Usability heuristics'). Participants described how the PWP and the computerised-program uniquely and collectively contributed to different WA needs.

64 Conclusions: This study was the first to offer a preliminary conceptual framework of WA in
65 b-CBT for depression, and how such demands can be addressed through blended PWP-program

delivery. These findings can be used to promote WA in technological design and clinical
practice, thereby promoting engagement to b-CBT interventions, and the effective deployment
of practitioner and program resources.

69 Trial registration: E-Compared Trial, ISRCTN registry, ISRCTN12388725. Registered on 20
70 March 2015.

Keywords: Working alliance, blended psychological interventions, cognitive behavioural blic invo. therapy and patient and public involvement.

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Article summary

Strengths and limitations of the study

- Patient involvement enabled the project aims to be grounded on the needs and interests of people who have experienced mental illness and service-use, in order to enhance the application of the findings.
- Bordin's working alliance (WA) theory was adopted to explore within b-CBT due to the theory's comprehensive description, its' pan-theoretical nature, and its' openness to adaptation in relation to different therapeutic formats.
- The studies' sample is limited to 19 individuals with a primary diagnosis of mildto-moderate depression, mostly reporting moderate to high WA and were largely male, British white and university educated individuals, thereby restricting the generalisability of our findings.
- Exposure to only one type of digital program, may have influenced participant's experience of WA (e.g. a computerised platform that doesn't work adequately might generate more data on the importance of 'ease of use', than one that does), limiting the breadth of data collected on the working alliance.
- Efforts were made to strengthen the conceptual framework through interview topic guides which were guided by Bordin's WA theory, patient involvement input, and a data analysis approach which avoided surface level themes, specific to technological design.

78 INTRODUCTION

Mental health conditions impact one in six people in the European Union, resulting in an estimated economic burden of over €600 billion.[1] The treatment gap in the region remains high with 35-50% of people experiencing mental health concerns not accessing treatment.[1] The wide disparity between mental health care needs and access to services has prompted calls for the strategic deployment of technology to facilitate and expand access to mental health services at a lower cost.[2,3] In the past decade, an increasing number of studies have investigated the efficacy of computerised cognitive behavioural therapy (c-CBT), a type of digital intervention that delivers CBT via interactive presentation features.[4] The implementation of c-CBT is generally either unguided (led by a computerised program with no external support), guided (led by a computerised programme and typically supported by a nonspecialist facilitator) or blended (led by a therapist, incorporating a c-CBT programme, or led by a c-CBT program and supported by a therapist), with the latter approach offering the highest level of therapist support[4,5]

The evidence for c-CBT has demonstrated equal benefits to face-to-face CBT for a range of mental health conditions.[4] However, these findings largely hold true when digital psychotherapies are guided by a human facilitator. Higher support from a therapist or another human facilitator appears to be related with better adherence and clinical outcomes.[6] The effects of human support on engagement with c-CBT raises important questions about mechanisms that support positive change in c-CBT. This has led scholars to consider the applicability of established mechanisms of change derived from conventional psychotherapies, to 'blended' formats. Particular interest has centred on the construct of the client-therapist allianceⁱ (therapeutic, working etc.).[7,8] While the concept of the alliance has taken root in a

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number of therapy approaches, Edward Bordin[9] drew on their commonalities to formulate a
pan-theoretical theory called the working alliance (WA) originally defined as:

"a formation between the client seeking change and the therapist offering to act as a
change agent that incorporated a mutual understanding and agreement about change
goals and the necessary tasks to move forward these goals along with the establishment
of bonds to maintain the partners' work".[9,10] (pg. 13)

Here, the 'task' refers to an agreed-upon contract that specifies the activities used to work on the client's goals. 'Goals' entails the exploration and review of what the client wants to achieve in therapy, while the 'bond' relates to the perceived compatibility between the client and the therapist, and the partnership that stems from shared activities.[9,10] Central to Bordin's[9,10] conceptualisation, is the collaboration and consensus between the therapist and the client, in order to promote meaningful engagement with the intervention.

The alliance has consistently been found to predict positive therapeutic outcomes. A keystone meta-analytic review found that the therapeutic alliance accounted for more variance (30%) than the therapeutic technique (15%) and therapy expectancy (15%).[11] This allianceoutcome relationship finding, was mirrored in recent meta-analyses, one of 191 varied therapeutic studies (r = .28 [95% CI: .25 to .30]),[12] and another focusing on CBT interventions for depression (r = .26 [95% CI: .19 to .32]).[13]

A growing body of literature on the alliance in internet-based psychological interventions indicate that the quality of the alliance in guided psychotherapy programs and b-CBT may be equal to or better than traditional formats of face-to-face therapy.[14–16] There is also evidence to suggest that the client reported alliance in guided c-CBT is directly associated with treatment outcome.[17,18] However, c-CBT may place different demands on the alliance. A narrative review evaluating WA in supported c-CBT interventions found that while significant Page 9 of 51

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associations were found between the task and goals sub-scales of WA, and treatment outcome, none were found for the bond subscale.[18] Qualitative research on the alliance in unguided mental health interventions also indicates that cCBT may offer additional alliance benefits such as higher control and autonomy.[19,20]

Taken together, these findings underscore the importance of developing a guiding framework for understanding the nature of WA in b-CBT, amidst a gradual movement towards shared mental health care delivery between human practitioners and digital technology.[21] Our study therefore aims to examine the WA demands through patient involvement and participant qualitative interviews, to adapt Bordin's[9,10] conceptualisation of WA for a b-CBT intervention for depression.[22]

METHOD

Patient and public involvement

Patient advisors were enlisted at a pre-research data collection stage to collaboratively examine WA in a digital CBT program without human support. Patient advisors were not involved in the recruitment of participants or of conducting the study. Patient involvement included eleven advisors with experience of mental health service use, predominantly for mild-moderate depression (n=7), but also for anxiety (n=1) and severe mental health conditions (n=3)ⁱⁱ. Advisors attended two meetings in the summer of 2015. The first meeting consisted of a comprehensive pre-involvement preparation briefing, to provide advisors with the knowledge and skills that would enable optimal conditions to aid their role.[23] Advisors were also provided with access to a computerised CBT for depression program called Moodbuster (program used on the E-Compared trial),[24] which they were encouraged to test and review in their own time, to provide context for discussion.[23] Advisors voluntarily tested all components of the Moodbuster intervention between meetings. In the second meeting, advisors

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were split into three small focus group discussion interviews, to facilitate the sharing of personal experiences and enable a higher level of opportunities to participate.[25] Discussions attempted to address three pre-patient involvement objectives, including: (i) is WA, as defined by Bordin[9,10] relevant in the context of a digital program intervention? (ii) What are the intrinsic WA demands between the client and digital provider? and (iii) Can digital delivery offer new ways of building WA, above and beyond Bordin's [9,10] bond, goals and task? The three focus group discussions were audio-recorded using an Olympus digital voice recorder WS-852, transcribed, and analysed to identify thematic patterns and themes. Patient involvement contribution was reported in line with version 2 of the Guidance for Reporting Involvement of Patients and the Public Short Form (GRIPP2-SF).[26] Patient advisors were thanked for their contribution after their involvement and also in the acknowledgements of this paper. The results of the study will be disseminated via a lay summary of the research, which will be supplemented with a peer-reviewed publication.

Patient involvement was instrumental in shaping the focus of the study and in guiding participant interviews in three different ways: First, patient involvement input suggested that Bordin's [9,10] WA as a function of enhancing engagement, was both relevant and important in the context of a digital psychological intervention. Second, the focus of the planned participant interviews changed from exploring WA within a computerised CBT (c-CBT) intervention only, to exploring the shared therapist-program format of CBT, as advisors unanimously suggested that some WA needs (especially bond and elements of support) could not be satisfied without human facilitation. Third, we set out to extend Bordin's [9,10] WA theory as patient involvement suggested that the c-CBT program could lead to additional alliance building and maintenance features.

Design

4	175	Design
5 6	176	A qualitative methodology design was used to gain an in-depth understanding of WA with
7 8	177	participants who experienced b-CBT on the E-compared trial.[24] E-compared is a non-
9 10 11	178	inferiority, pragmatic trial that evaluated the cost effectiveness of b-CBT for depression, when
12 13	179	compared to usual care, across eight countries in the European region. [24] Potential
14 15	180	participants from the UK were referred from primary care services by clinical staff, if they
16 17 18	181	scored 4 points or higher on the Patient Health Questionnaire-9,[27] and if they were interested
19 20	182	in receiving b-CBT for depression. The b-CBT intervention consisted of 11 blended low-
21 22	183	intensity CBT sessions, six with a low-intensity psychological wellbeing practitioner (PWP ⁱⁱⁱ)
23 24	184	(average duration of 30 minutes) and a least five at home via a synchronised computerised
25 26 27	185	platform and mobile-application called Moodbuster. The treatment course spanned across 11
28 29	186	weeks. There were four mandatory core modules of CBT on the digital platform (psychological
30 31	187	education, behavioural activation, cognitive restructuring, and relapse prevention) and two
32 33 34	188	optional modules (physical exercise and problem solving) that were completed autonomously
35 36	189	at home. The low-intensity PWP in the clinic encouraged participants to use the computerised
37 38	190	programme in different ways. The PWP could introduce modules, review if the client had
39 40 41	191	completed modules, or guide the client on the use of specific modules). Clinic and face-to-face
41 42 43	192	sessions were alternated, however there was flexibility in the sequence of the delivery mode
44 45	193	and the order in which the modules were completed, including opportunities for the PWP to
46 47	194	use bespoke tasks. Additional information about the trial and the b-CBT intervention can be
48 49 50	195	accessed from the trial protocol by Kleiboer and colleagues.[24]
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Participants

E-Compared participants from the UK were invited to take part in qualitative interviews. Trial participants aged 18 years or older with a clinical diagnosis of Major Depressive Disorder (MDD), were enrolled in the study.[24] People with substance abuse, suicidal tendencies, other

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severe psychiatric disorders, cognitive disability or people who had insufficient knowledge of English were excluded. Psychiatric diagnoses were confirmed by the MINI International Neuropsychiatric Interview (M.I.N.I) version 5.0.[28] E-Compared trial[24] participants who: (a) provided written consent to the qualitative interviews when they enrolled on the trial (n=101); (b) were randomised to the b-CBT arm (n=49); and (c) had completed at least one computerised module and face-to-face session (n=42) were purposively sampled to be representative of the b-CBT arm, in relation to their sex, age, and recruitment site.[29] Altogether, 26 out of 42 people were invited to take part in the qualitative study, with 19 re-consenting to participate. Reasons for non-consent included scheduling conflicts (n=2) nonresponse to invitation (n=4), and change in eligibility status due to erroneous information about arm allocation ($n=1^{iv}$).

Procedure

E-compared participants were invited to take part in face-to-face individual semi-structured qualitative interviews, at least 2 weeks after they completed their course of therapy on the trial. This was to provide participants with enough time to reflect on their experience of the b-CBT intervention. Potential participants were invited to take part in interviews about their experience of b-CBT, and were emailed a patient information sheet following their initial correspondence with the research team. Participants were provided with at least 48 hours to read and consolidate the information, before they were followed up and booked in for a qualitative interview at an acceptable time and place. Written consent for their participation, as well as audio recording of the interview, was sought again prior to starting their interviews and were reminded of their right to withdraw at any time and without giving a reason. Data collection took place until saturation was reached.[29] The study adopted Corbin and Strauss's definition of saturation, which is described as the point where further data collection becomes 'counter-productive', and where 'new' themes do not add anything to the overall narrative of the story.[29] Saturation

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was monitored through writing memos after each interview, in which information on both keyand novel emerging themes from the interview were recorded.[29]

The project was approved by the Health Research Authority's Ethics Committee on 17th April
2015 (REC reference: 15/LO/0511) and the London School of Hygiene and Tropical Medicine
Research Ethics Committee on 9th June 2015 (Ethics Ref: 9409).

230 Measures

Self-reported WA and symptoms of depression, collected on the E-Compared trial[24] were reported to further describe participant characteristics (in addition to sociodemographic data) and to provide insights on WA and the level of depression experienced by the participants on the study. Self-reported WA was assessed through the Working Alliance Inventory Short Form - Client (WAI-SF-C).[30] Scores for the 12 items on WAI-SF-C range between 12- 60. Scores were divided into 3 groups to produce a low-range (12-28), medium-range (29-44), and high-range (45-60) to indicate the level of WA reported by each participant. Higher scores indicate better WA. Self-reported depression was assessed through the Patient Health Questionnaire-9 (PHQ-9).[27] Scores for the 9 items on the PHQ-9 range between 0-27. Higher scores indicate more severe symptoms. Data was collected during the trial's three months follow-up assessments.[24]

242 Guiding framework

Our study adopted Edward Bordin's[9,10] theory of WA to explore in the context of b-CBT for three reasons. The first relates to the generalisable nature of the theory. While the concept of the alliance stemmed from psychodynamic theory in 1912, it has since been incorporated in various therapeutic approaches, leading to heterogeneity in the way the concept is defined.[12] In 1979, Bordin[9,10] attempted to unify the way the alliance is defined, by proposing a pantheoretical conceptualisation[9] that drew on the key features of all therapeutic approaches.[12]

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Second, Bordin's[9,10] theory is operationalised as task focused,[12] and therefore offers a suitable fit for task-orientated psychological approaches such as CBT.[31] Third, the theory is open to adaptation. Bordin[9,10] suggested that while a pan-theoretical approach allowed the basic measurement of the bond, goals and task to produce beneficial therapeutic change, he also suggested that the ideal alliance *profile* is likely to be different across therapeutic approaches and interventions.[9,10,12]

256 Data collection

Data collection took place between October 2016 and July 2017 across four primary care mental health services in the UK. Qualitative interviews were adopted to enable a detailed examination of the participant's personal experiences and perspectives of WA within the context of their experience of receiving b-CBT. The study predominately included a deductive approach to exploring WA in b-CBT based on Bordin's[9,10] theoretical framework, while remaining open to novel or unexpected inductive new findings. On average, participant interviews lasted around 47 minutes. Interviews were conducted in a confidential setting within a university campus or the health service which the participant was recruited from. All interviews were audio-recorded using an Olympus digital voice recorder WS-852 and transcribed to produce orthographic verbal verbatim. AD (female) conducted the qualitative interviews, was a PhD Candidate with experience of conducting and analysing qualitative data. Semi-structured interviews with a conversational technique were used to achieve a balance between the need for consistency of questioning across participants, and the ability to explore topics that are important to the participant. During interviews there was also scope to allow topics covered to evolve iteratively based on the emerging data. [29,32] The development of an interview topic guide was supported by patient involvement input and guided by the WA theory[9,10]. The initial topic guide was used to suggest topics of discussion, and not as a

Page 15 of 51

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definitive framework to limit conversations. As the data collection progressed, the topic guides evolved iteratively based on emerging themes. Subsequent interviews were therefore influenced by interviews that previously took place, providing opportunities to validate and refute interpretations.[29]

279 Data analysis

A preliminary data analysis took place alongside early interviews, allowing subsequent interviews to progress iteratively.[29] Memos were written after each interview, to aid the preliminary analysis and iterative adaptation of the topic guide and to propose possible relationships between codes. Thematic analysis was adopted due to the theoretical flexibility, as well as the 'thick descriptions' afforded by the approach.[33] The data analysis incorporated a constant comparative method from grounded theory, to enable the analyst to search for new theoretical models that are grounded in empirical data, and to enhance the trustworthiness of data.[29]

The lead analyst (AD) commenced the data analysis by reading through the transcripts, while listening to the audio recording and reading the corresponding memos. The analyst then actively re-read the data, searching for meaning, and noted down initial concepts. Data was coded line-by-line. Codes were generated by searching for interesting features across the entire dataset and collating data relevant to each code segments. The emerging codes were clustered into categories and labelled thematically. Once the data was initially coded and collated, the analyst commenced searching for themes that were compatible with Bordin's [9,10] WA theory and patient involvement input, while also searching for novel alliance concepts. Themes were located at a latent level, to delve beyond the semantic content of the data, to identify and examine underlying ideas, assumptions, conceptualisation and ideologies that theorise

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semantic content of the data.[33] The initial codes were gradually merged into broader categories through comparison across transcripts, to identify overarching themes. The themes were then reviewed to ensure that the codes cohere together meaningfully, while maintaining a clear and identifiable distinction with no overlap between the themes. Finally, the themes were reviewed to consider their relationship to the overall thematic map. Once a thematic 'map' was identified, the findings were developed into a conceptual framework of WA in b-CBT.[33]

Two other members of the research team (CF and DM), who are highly familiar with qualitative methodologies and Bordin's[9,10] WA theory, read through 20% of all transcripts and reviewed all supporting quotes across all phases of the analysis, so that close to half of the transcripts were reviewed. Discrepancies were discussed and reconciled. The final framework was discussed and revised over eight meetings. The entire coding process was performed using the NVivo 11 data analysis software package. Supporting quotes were anonymised to ensure that that participants and their PWP could not be identified.

To ensure the final conceptual framework accurately reflected WA, a 'therapeutic process', was not confounded with early manifestations of 'treatment outcomes' we defined "therapeutic processes" relevant to WA, and the 'treatment outcomes' associated with CBT.[30] 'Therapeutic processes' was defined as "actions, experiences, and relatedness of the client and the therapist in therapy sessions...". [34] We a-priori extended the use of the term 'therapy session' to include face-to-face and digital delivery in the context of blended therapy. Horvath and colleagues[30] noted three ways of defining the outcome in psychotherapy including: (a) the core value attributed to the outcome by the client, (b) the importance of the outcome in the theoretical framework of the therapist, and (c) the utility of the outcome (e.g. the technique) to promote other outcomes that are valued. We defined outcome in relation to definitions b and c to enable a standardised definition that does not vary from client-to-client (i.e., definition a). We a-priori define the outcomes of CBT as the alleviation of distress (b) through helping the

Page 17 of 51

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client to develop more adaptive cognitions and behaviours *(c)*.[31] The final conceptual framework was reviewed in light of the aforementioned definitions by members of the research team. Themes and sub-themes that were judged to correspond with the definition of 'treatment outcome" were removed. We used the SRQR checklist when writing our report.[35]

- ² 327
 - 328 RESULTS

Description of sample

An exploration of WA in b-CBT was undertaken through 19 qualitative interviews with participants who experienced b-CBT in the treatment arm of the E-Compared trial[24]. Participants were aged between 19-67 years (Mean=34.47 years, SD=14.44 years), largely male (n=13), white British or white other (n=12), and university educated (n=12). All interviews were conducted face-to-face apart from one, which was completed by phone. Saturation appeared to be reached by the 16th interview. Another three interviews were carried out to ensure that the selected saturation cut-off point had been accurately identified and to further validate interpretations. Tables 2-4 show that the main themes were endorsed by 89% -100% of participants, indicating that the selected saturation cut-off point was sufficient.

Table 1. Sample characteristics	of participants who took part in t	the qualitative interviews (n=19)
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Characteristics	Mean (SD) or Percentage (<i>n</i>)
Age in years	34.47 (14.44) range 19- 67 years
Gender (male)	69% (13)
Marital status	
Divorced	5% (1)
Living together	11% (2)
Single	63 % (12)
Married	21% (4)

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Highest educational level completed	
Secondary School, equivalent	11% (2
Colleague, equivalent	26% (5
University degree or higher	63% (12
Ethnicity	
British white or white other	63.1% (12
Black/African/ Caribbean / Black British	5.3% (
Asian or Asian British (Any other Asian)	21% (4
Mixed or Multiple Ethnic Group	5.3% (
Other	5.3% (
Intervention completion level ^a	
Completed course of b-CBT	63.2% (12
Incomplete course of b-CBT	36.8% (1
WAI-SF-P ^b	46.29 (SD=10.21), score range 27-60 (17
High WAI-SF-P	score range 47-60 (1
Medium WAI-SF-P	score range 31-41 (
Low WAI-SF-P	score 27 (
No score	(4
PHQ-9 <mark>°</mark>	7.8 (6.87), score range 1-22 (n=18

^a Intervention completion level: A complete course of b-CBT refers to the completion of four mandatory Moodbuster modules (psychological education, behavioural activation, cognitive restructuring and relapse prevention), while an incomplete course of b-CBT course refers to the non-completion of the four mandatory Moodbuster modules.

^b WAI-SF: Working Alliance Inventory Short Form. Four participants did not provide data for this questionnaire during their 3 month follow-up assessment.

°PHQ-9: Patient Health Questionnaire-9.

341 Conceptual framework of WA in b-CBT

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A thematic analysis with a constant comparative method^[33] revealed multifaceted WA demands which show that the work of building WA in b-CBT involved a symbiotic effort by the PWP and the digital program, to actively engage the client to meaningful therapeutic activities and to promote self-discovery and commitment to the intervention. Such demands can be grouped into four overarching WA themes, (1)'bond', (2)'task', (3)'goals' (in line with Bordin's [9,10] WA theory categories^v) and (4) 'usability heuristics' (a newly emerging theme) (See Fig. 1 for a summary of the main themes and sub-themes).

Theme 1: Bond

The 'bond' is defined as a set of mental health care provider (including both the PWP and computerised program) competencies that enable a working relationship to be established and maintained with a client. Participants unanimously reported that a human therapist was the most important facilitator for building the bond in a b-CBT context. This was because participants valued qualities of 'humanity', and 'responsiveness' attributed to a human therapist. Through a process in which participants appeared to compare and contrast the strengths of the digital program with the PWP, most participants questioned the 'meaningfulness' of interacting with a digital platform that was incapable of understanding or responding to a client's needs as demonstrated by the following quote:

"an app is like a machine, it's not personal at all. I think it's good to have some element[s] of talking to a human about this kind of thing because I think you want reassurance as well, which you wouldn't get from an app and if you did it would just be responses built in".

(P8, M, 24 y/o, low-range Working Alliance Inventory Short Form - Client (WAI-SF-C))

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> Data from participant interviews revealed three broad PWP attributes considered to be important for the bond building process, namely the mental health providers' ability to; effectively demonstrate their understanding of their client's struggles and needs (sub-theme 1.1); convey that they are genuine in their endeavours towards the client (sub-theme 1.2); and forge a working partnership founded on friendliness, feeling cared for, empathy and trust (sub-theme 1.3) (see Table 2 for sub-theme descriptions and supporting quotes). Some participants elaborated on these concepts further to unearth granular insights of what it means to be in the presence of a PWP. Visually observing a PWP's non-verbal cues was reported to be especially important for gauging abstract relational concepts such as empathic understanding (sub-theme 1.1), and genuineness (sub-theme 1.2). The recognition of positive non-verbal cues appeared to increase congruence between the PWP and the client (sub-theme 1.3) throughout the course of therapy:

> "[During telephone therapy] he was like "mm hm, go on ...so how do you feel?" I
> can't see his face. I don't know what he was thinking. I can't feel him. But during
> face-to-face [sessions] I think when I talk about something I can notice, his or her like
> facial expression. I know he's listening ... That make[s] me feel like talk[ing] more".
> (P14, M, 34 y/o, WAI-SF-C score not available^{vi})

Table 2. Theme 1, bond sub-theme descriptions and supporting quotes

Supporting quotes	
P12, M, 23 y/o, high-range WAI-SF-C score:	
"My therapist did make a real effort to try and get to know me, try to	
maybe get to know what made me tick and why I was feeling how I	

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2				
3		what is being said and demonstrate	did, rather than just assuming this is what you need without taking	
4 5		empathic awareness and insight into the	into account maybe what I as a person, personally needed".	
6				
7		client's concerns.		
8 9				
9 10				
11				
12		1. 2 Genuineness, 32% (6)	P9, M, 24 y/o, low WAI-SF-C score:	
13 14		The PWP's efforts to help the client, that	"To be honest, I kind of felt like she [PWP] was very fakeEvery time	
15		are perceived as genuine and authentic, as	I'd say something there would be an, ahh, it just felt not genuine at all,	
16				
17 18		opposed to procedural or routine.	that she was just saying it because she thought I felt down"	
10 19				
20		1.3. Partnership, 74% (14)	P12, M, 23 y/o, high-range WAI-SF-C score:	
21				
22 23		The ability of the client and PWP to	"I feel like she, as I said earlier, took the time to get to know me and	
24		achieve a working relationship that is akin	what I was currently doing, so it did feel like she kind of knew me	
25 26		to a friendship. Such a partnership is	on an individual level, rather than just being the patient."	
27 28		characterised by trust, feeling liked and		
29 30		feeling cared for.		
31		*WAI-SF-C: Working Alliance Inventory Short Form- Client.		
32	205			
33 34	385			
35				
36	386	Theme 2: Goals		
37 38				
39	387	'Goals' refers to the collaborative work between the PWP, the client and the digital interface,		
40				
41 42	388	to appropriately identify what the cli	ient hopes to achieve through therapy (68% of sample	
42	200	-12		
44	389	endorsed the goals theme, n=13). w	'hile 'goals' emerged as a distinct factor, it also appears	
45	390	to be interrelated with the 'task', thereby playing a fundamental role in framing activity-based		
46 47	550	to be interretated with the task, there	by playing a randamental fore in naming derivity based	
48	391	tasks and maintaining the client's mot	ivation to work towards creating change.	
49		U	5 5	
50	202	"The goal setting getually was	something that I spoke to [the PWP] quite a bit about in	
51 52	392	The goal setting actually was	sometning that I spoke to [the F WF] quite a bit about th	
53	393	the session [] I was then like	e "God well what are my goals? [] what, where am I	
54	000			
55 56	394	exactly going?" (P5, M, 22 y/c	o, higher-range WAI-SF-C score)	
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396 Theme 3: Task

The 'task' refers to the careful selection and acceptability of the therapeutic activities prescribed to address the client's presenting symptoms ('activity-based task'), and the degree to which the support received by the healthcare provider on these activities is responsive ('responsive support').

The defining features of 'activity based-task' refers to the client's ability to work on tasks that are; personalised and acceptable for addressing the client's therapy goals (sub-theme 3.1); useful in promoting new learning, insights and reflection (sub-theme 3.2) and are complimentary across both modes of delivery (sub-theme 3.3). The defining features of 'responsive support' relate to the provider's (largely referring to the PWP's role) ability to appropriately respond to a range of clients' expressed and unexpressed need to; maintain accountability (sub-theme 3.4); provide activity-based guidance (sub-theme 3.5); and have a safe-space for clients to express their feelings and emotions (sub-theme 3.6) (see Table 3 for sub-theme descriptions, and supporting quotes).

Table 3. Theme 2, task sub-theme descriptions and supporting quotes

Theme, percentage of sample endorsed (<i>n</i>)	Supporting quotes
and description	
THEME 3: Task 100%, (19)	
Activity-Based Task, 100% (19)	
3.1. Personalisation, 95% (18)	P12, M, 23 y/o, high-range WAI-SF-C Score:
The level at which a client is able to tailor the	"I think it's a bit more personalised, because I would say
therapeutic task to their individual needs. A non-	whilst the E-Compared is good, it is still, it is to an extent
personalised digital intervention was reported to	generic, because it can't kind of know every single person
negatively impact engagement. The PWP in	that's watching the video, so whereas the therapists can kin
blended-therapy can play an important role in	of get an idea of you, your story, your journey, what's maybe
making a generic intervention (i.e. computerised	led you to kind of this maybe relapse, or for you to be feeling
CBT) as more personalised.	the way you are, and you can't maybe get that from a

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59 60 computer...Whereas if I'm hearing it from the person, I'm going to take a bit more notice, but then if I'm just hearing it from the computer, where it will say that to everyone watching the video"

3.2. Usefulness, 95% (18)

A useful task was defined as one that promotes new learning, reflection and is effective in creating desired change in the client's life.

P4, F, 18 y/o, medium-range WAI-S-C score:

"But like the modules themselves, feelings-wise they were often quite helpful for clarifying stuff. Like I usually came out the other end feeling better or more kind of composed...it would kind of shape how I was seeing things. So like if I, you know learned about thought distortions, I'd kind of go in with that knowledge and be able to kind of talk about it..."

3.3. Complementary, 84% (16)

The ability to experience complementary tasks in face-to-face therapy and on the digital platform as continuous and cohesive, as opposed to stilted and disjoint. Knowing what to expect from the respective components of blended therapy was reported to help the client optimise the benefits sought from different components of therapy.

P16, F, 35 y/o, medium working alliance:

"I was finding it really hard to leave the house so that whole thought of going to therapy was quite difficult in the very beginning, so it did take me a couple of sessions to really start talking to [therapist] and opening up but because I had this online support I found it easier to open up to [therapist] so maybe instead of you know, two sessions it would have taken four or five."

Responsive support Task, 100% (19)

3.4. Accountability, 79% (15)

The availability of a figure of authority that the client can (positively) feel responsible towards, as a means of garnering motivation to work on therapeutic activities. For the process of accountability to positively impact the client's motivation, a **PWP** is required to demonstrate their knowledge of the client's progress and provide feedback accordingly.

"Oh right, OK. Well, to me, I saw it like homework, you've got to get it done otherwise you get into trouble, not that I would have got in trouble, but do you know what I mean, you're sort of motivated that way. And there is the other, the embarrassment of going in and saying 'oh yeah, I didn't do the modules' and then you feel really about that big and you know, someone's trying to help you and you haven't bothered to do your bit kind of thing. So that was a motivation in itself."

P19, M, 59 y/o, medium-range WAI-S-C score:

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37 38	
39	
40	1
41 42	4:
42	4
44	
45 46	4
40 47	
48	4
49 50	4
50 51	4.
52	4
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54 55	4
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3.5. Guidance, 89% (17) The provision of guidance and reassurance on the therapeutic tasks by a **PWP**. The PWP's intuition, expertise, interpretation and foresight is especially considered as helpful in addressing salient issues that would not have otherwise been communicated by the client.

P10, M, 45 y/o, high-range WAI-SF-C score:

"When you speak to your therapist, obviously she's had a lot of different scenarios with a lot of different people, she's got the experience and the know-how, and then obviously how I'm looking at it thinking the module's really working like this, she then says, "That's really brilliant, but to then add onto that and to support you, how about if you think about that?."

3.6. Expression of feelings 100% (19)

The client's expressed need to speak to another human being, in order to communicate issues that are pertinent to their treatment journey. In order for the client to optimally benefit, clients require the PWP to dedicate a sufficient amount of time for the activity. The amount of time required by each person appears to vary in relation to pre-therapy expectations and symptom severity.

P14, M, 34 y/o, WAI-SF-C score unavailable:

"I think it's nice to have someone to talk to. It's kind of, I think it's important for me to express my feelings like in a private situation. Because sometimes I have, kind of I live with my partner but, you know, some[times], you can't talk to her."

WAI-SF-C: Working Alliance Inventory Short Form-Client.

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The majority of participants noted the importance of experiencing the therapeutic activity as 12 complementary across modes of delivery (sub-theme 3.3). Some participants elaborated that 13 14 an initial step to achieving an effective symbiotic delivery was to provide the client with an understanding of how the PWP and digital delivery contributed towards their treatment both 15 distinctively and collectively. 16

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418 Our findings also suggested that the ubiquity of c-CBT appeared to positively impact the client419 PWP WA, through increased opportunities to reinforce what was learned through the digital
420 platform, with a PWP, and vice-versa, for instance:

421 "Well I think it gave you something to do over and above the face-to-face ... having the
422 modules to go through, it reinforces what you're talking about face-to-face and makes
423 it easier to understand. It's, that repetition thing isn't it where you learn by repetition
424 basically and that's how I saw it working."

425 (P17, M, 39 y/o, WAI-SF-C score not available)

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427 Theme 4: Usability heuristics

The final alliance building theme identified is, 'usability heu s', which refers to the process of predominantly using technology to promote active agement, self-discovery and autonomous problem solving in b-CBT. This category is a n component to Bordin's[9,10] theory. Features that enable 'usability heuristics' include ut tous digital technologies that; increase access and immediacy to the therapeutic task (sube 4.1), appropriately respond to the client's input (sub-theme 4.2), are easy to use (sub-the 3) have aesthetic appeal (sub-theme 4.4) and promotes self-directed therapy (sub-theme (see Table 4 for sub-theme descriptions, and supporting quotes).

While PWP competencies emerged as the most important fa ator for building the alliance, almost all participants expressed that they preferred blend sychotherapy to face-to-face therapy alone. Some participants elaborated that their abilit access the intervention at any time or place of convenience (sub-themes 4.1) further bolster eir engagement to therapeutic activities (theme 2). Participants who reported a high technological affinity suggested that the appearance (sub-theme 4.4) and ease of use (sub-theme 4.3) of the interface impacted their

perceptions of the digital program's credibility and therefore, their desire to engage in treatmentactivities.

Almost all participants reported that the digital program provided them with the tools to initiate treatment independently (sub-theme 4.5), with some participants noting that they continued to use the digital program as a means of maintaining therapeutic gains once their therapy course had ended. Here, autonomous completion of the therapeutic task was described as a securebase that allowed clients to progressively explore self-directed therapy:

"it kind of reminds me of Winnicott and the Secure Base in Attachment theory in psychology, that you know, children become securely attached if they have a secure base in terms of the home and the parents that they can come back to, so they can go off and explore the world confidently in the knowledge that they can come back to security, and that, that helps them to develop - and it's kind of like that, I feel, with having that Moodbuster resource [digital program] there, that you can keep coming back to it ... there is a lot in there and you can keep going back and it's a sort of source of strength really".

457 (P10, M, 51 y/o, higher-range WAI-SF-C score)

458 Participants suggested that the blended approach prepared the client to engage in autonomous459 self-directed therapy, through a process of supervised autonomy.

Table 4: Theme 4, Usability heuristics, sub-theme descriptions and	supporting quotes
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) and Supporting quotes	entage of sample endorsed (<i>n</i>) and
	description
	ability heuristics, 100% (19)
	ability heuristics, 100% (19)

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4.1. Accessibility, 95% (18)

The ability of a client to access the digital intervention at a time and place of convenience. Higher accessibility provides opportunities for the client to review and reflect on what has been learned at a deeper level.

4.2. Interactivity, 63% (12)

An interactive digital program that is able to react to the clients input, to produce feedback. Interactive activities were perceived as more enjoyable, and promoted a degree of accountability.

4.3. Ease of use, 63% (12)

The ease of use of the digital interface is described as a well-functioning, intuitive, digital interface which enables optimal access to the therapeutic task.

P10, M, 45 y/o, high-range WAI-SF-C score:

"Being on your own you know, in your own time and in your own safe place, your blanket, whatever you call it just allowed me personally just to open up and look at it, and then going from the start of the process to the end, ... thinking positively, looking at your behaviours, looking at adding little things in and then the exercise at the end, rewarding yourself for just achieving things what I felt at the time were trivial made everything different."

P6, M, 22 y/o, high working alliance:

"One thing immediately comes to mind, it has to be a bit more interactive I think. The client shall we say, as well I feel should be given more feedback, the results, you know when you're scoring yourself on those, what that's about you know, how do they interpret that score, when you're putting your mood in on the smartphone, what's that about you know, who's looking at that, who's interpreting that".

P2, F, 23 y/o, high-range WAI-SF-C score:

"It was really nice, I thought it was really, well very well presented I would say, and everything was just there, like for easy viewing, so you didn't have to like go through like folders or like go deeper into the website, like it was just there, and you know, I could just easily click on what I needed to do and just follow the instructions set out on the exercises."

4.4. Aesthetic appeal, 21% (4)

P13, M, 24 y/o, medium-range WAI-SF-C score:

The appearance or appeal of the digital interface is a factor that clients use to judge the credibility of the digital intervention and which could impact their engagement to the therapeutic task. "Yeah, and actually it became quite a bit of work just keeping up with the calendar, sort of, I found it a bit clunky, but then I worked in I.T for sixteen years...". 4.5. Self-directed, 79% (15)The process of taking responsibility for one's own behaviour and well-being, appears to instil clients with a sense of independence and control.

P3, F, 19 y/o, medium-range WAI-SF-C score: "Other times it was good kind of to do a time and also independence, kind of learning to do stuff without a therapist there...I quite liked that I could, I don't know for me because it, I suppose it ties back into the independence thing, but because I was doing it on my own I almost proved I could do it on my own...because I feel like sometimes with a therapist you almost become like dependent on them or, it's like being taught something, when you're like dependent on the teacher."

WAI-SF-C: Working Alliance Inventory Short Form – Client.

DISCUSSION

462 Statement of principal findings

The results of the study present a preliminary conceptual framework of WA in b-CBT. It can be seen that Bordin's [9,10] 'bond', 'goals' and 'task' appear to be relevant in blended formats of CBT, however the priorities of WA demands have shifted to meet the client needs within a blended format. Moreover, an entirely new category 'usability heuristics', emerged as a novel means of promoting a new level of WA through a process of self-directed discovery and autonomous problem solving. Participants also explained that different modes of delivery by the PWP (e.g. client-provider bond, responsive support) and the digital program (e.g., upholding goals, task and promoting usability heuristics) were useful for meeting different WA demands.

472 Strengths and limitations of the study

473 Based on our search, this study seems to be the first to provide an account of WA in b-CBT,474 and insights on how different treatment roles within a blended format of therapy, are used to

Page 29 of 51

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meet different WA demands. This is especially important given that, digital technologies are increasingly being used to treat mental illness,[4] and that WA plays an important role in promoting positive therapeutic change.[12] The design of our study had two key strengths. First, we used the most comprehensive and commonly used theory of the 'alliance' to approach our study.[36] Second, involving patient involvement enabled the project to be grounded on the needs and interests of people who have experienced mental health conditions and service use, thereby enhancing the application of the findings.[23] There are also several limitations to be noted. Our study does not include the PWP's perspective, which may have provided additional insights on WA in b-CBT, [18] however, this will be explored in a separate paper. Our sample was limited to 19 individuals with a primary diagnosis of mild-to-moderate depression who mostly reported moderate to high WA, were largely male, British white or white other and university educated, thereby limiting the representativeness of people seeking treatment in the UK[37] and restricting the generalisability of our findings. Exposure to only one type of digital program, may have influenced participant's experience of WA. For instance, a computerised platform that doesn't work adequately might generate more data on the importance of 'ease of use', than one that does. Some of these issues were pre-empted ahead of the study. Efforts were made to strengthen the conceptual framework in two ways. First, emerging participant data was guided by key literature on the alliance and patient involvement input. Second, our qualitative data analysis avoided the use of surface level themes, such as specific technological design. Instead, latent thematic analysis was used to unearth underlying psychological processes.[33]

497 Strengths and weaknesses in relation to other studies, discussing important differences in
498 results

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 Participants fed back that, while it was essential for therapeutic activities to be complimentary between modes of delivery, they also suggested that modes of delivery can uniquely meet different WA needs. For instance, participants unanimously fed back that the human PWP played an essential role in establishing the 'bond'. The role of the practitioner in supporting digital interventions is well documented in the literature.[6] A recent study evaluating the relationship between the client, the human provider and their c-CBT program, found that participants rated their overall treatment approach higher when they experienced c-CBT that was guided by a human provider compared to c-CBT that was unguided.[7] Another study evaluating the expectations of clients and practitioners in c-CBT for depression found personalised interactions with a therapist was key[38]. When attempts were made to unpack the importance of the therapist's role, participants suggested that the PWP's physical presence facilitated the PWP's propensity to convey important features of the bond (sub-themes 1.1-1.3) through verbal and non-verbal communication. This aligns with early psychotherapy research by Karl Rogers [39], who proposed that a therapists ability to display active listening (empathic understanding, unconditional positive regard, and congruent behaviour) was important for positively changing the impressions of the client's perceived negative experiences. Neuroscientific research evaluating the impact of active listening, suggested that the participant's recognition of active listening behaviour in another, can positively change the appraisal of an emotional episode and increased positive impressions of the active-listener.[40] These findings appear to be unique to human-to-human interactions. One study assessing the therapeutic alliance in a digital mental health mobile application for psychosis found that the anthropomorphizing of digital devices was not accepted by clients or mental health practitioners.[20] Given that little gains have been made to effectively deploy emotional artificial intelligence, a tool that is required for the effective biomimicry of human-beings in

Page 31 of 51

BMJ Open

the digital space,[41] the exclusion or non-effective deployment of a human provider in digitalpsychological interventions may therefore compromise the quality of WA.

On the other hand, participants reported that while the PWP was essential for the effective delivery of psychotherapy, participant's preferred blended delivery compared to PWP delivery alone. Almost all participants reported WA benefits, in the form of engagement, to digital delivery (i.e. 'usability heuristics'), through desired opportunities to engage in self-directed therapy. Our findings are echoed in the digital mental health user-experience and the alliance literature, which indicate that digital psychotherapy can enhance the client's perceived control, autonomy and feelings of empowerment, when sufficient human support is provided.[20,42] Our findings suggest that digital delivery within a b-CBT format cannot be disentangled from WA. For instance, a digital program that was perceived as non-interactive appeared to cause ruptures in engagement with 'activity-based task'. Given that digital delivery appears to have a significant impact on engagement with 'activity-based task', we argue that the inclusion of features that uphold existing alliance structures should therefore be accounted for in the WA framework. Our findings align with Bordin's [9,10] conceptualisation of WA, who proposed that the therapeutic tool cannot be disentangled from the means in which the alliance is built. This therefore suggests that the client-program WA can have an impact on the client-PWP WA, and vice-versa, contrary to research findings that suggest that WA contributions are independent and additive.[7]

The 'task' appears to play a central role in b-CBT, as initially theorised by Bordin[9,10]. Our findings appear to address Bordin's[10] call to distinguish between the task that is in service of 'building WA' (responsive support) and the tasks in the service of 'change' (activity basedtask). While many of the 'task' sub-themes appear to be novel to Bordin's[9,10] WA, with the exception of complementary tasks (sub-theme 3.3), all other 'task' sub-themes, are in fact implicit in his broad conceptualisation. The integration of technology in psychotherapy has Enseignement Superieur (ABES) . Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.

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prompted a re-evaluation of the demands placed on WA by a blended psychotherapeutic format. For example, the concept of accountability is implicit and forms one of many appendages associated with the PWP's role in building and maintaining WA. However, this concept has been propelled to the forefront as an essential ingredient for maintaining the alliance in b-CBT, in line with David Mohr and colleagues' 'supportive accountability' model for e-health.[43]

While 'bond', 'task' and 'heuristic' emerged as distinct themes, the 'goals' appears to be especially interlinked to the 'task'. The data from the qualitative interviews suggest that 'goals' was grounded in 'goals-setting activities'. This however diverges from Bordin's[9,10] description of the goals, which appears to move further, to address the PWP's efforts to unearth the core struggles that have bought the client to psychotherapy, in great detail[10]. One possible reason for our findings may be explained by the time-lag between the assessment and the first therapy session, which may have led participants to only focus on their course of b-CBT and not the proceeding assessment where more in-depth explorations of the client's struggles and goals generally take place. On the other hand, our study is not the first to question the operational distinctiveness of the 'goals' and the 'task'. The psychometric evaluation of the Working Alliance Inventory, based on Bordin's [9,10] WA suggested that concepts were highly interrelated,[30] while a more recent psychometric evaluation found that concepts did not emerge as distinct factors.[44]

568 Meaning of the study: possible explanations and implications for clinicians and ² 569 policymakers

570 Our findings address, at least in part, three of 10 clinical and research priorities of digital 570 technology in mental health care identified by people with lived experience of mental health 580 technology in mental health and social care practitioners (See Box 1).[8] WA, a common 590 conditions, carers and health and social care practitioners (See Box 1).[8] WA, a common Page 33 of 51

BMJ Open

element of psychotherapy appears to be both relevant and important in b-CBT for depression. Human delivery appears to be central to the maintenance of empathy, gestures and non-verbal cues in which the PWP role in b-CBT may focus on establishing the bond, and developing and maintaining the client's engagement through responsive support (Q8). Participants noted that both modes of delivery collaboratively contributed to the building of the alliance through distinctive pathways. While human support is perceived as 'responsive' and 'meaningful', digital delivery appears to promote autonomy and self-directed discovery (e.g. accessibility and self-directed therapy) and plays an important role in maintaining WA across 'goal' and 'task' activities (e.g. ease of use, interactivity of digital program and aesthetic appeal). Our findings appear to indicate that removing human support, seen as essential for the 'bond' and 'responsive support', may increase the risk of therapeutic ruptures and disengagement with psychological interventions delivered through a blended format (Q1 and Q3). These findings can be used to promote WA in technological design and clinical practice, thereby promoting engagement to b-CBT interventions for depression, and the effective deployment of PWP and digital support resources.

Box 1. Top ten research priorities for digital technology in mental health care, identified by the Priority Setting Partnerships [7].

Q1. What are the benefits and risks of delivering mental health care through technology instead of face-to-face and what impact does the removal of face-to-face human interaction have?

Q3. How can treatment outcomes be maximised by combining existing treatment options (medication, psychological therapies, etc.) with digital mental health interventions

Q8. Can the common elements of therapy (eg, empathy, gestures, non-verbal cues) that come from personto-person interactions be maintained with digital technology interventions?

589 Unanswered questions and future research

57 590 We propose four directions for future research. First, while our findings outline WA demands
58 59 591 in b-CBT, it is unknown if fulfilling such demands will lead to positive clinical change. Future

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> research should aim to investigate if self-reported WA as defined by our conceptual framework, predicts therapy outcome. Second, WA should be further explored across different computerised programs, clinical groups, higher-intensity interventions and other digital technologies (e.g. virtual experiences, gamification and text-based intervention) intended for use within a blended format, especially in relation to understanding the demands of different digital technologies in shaping 'usability heuristics'. Third, our findings can be used to inform the design of behavioural intervention technology theories, as a means of enhancing engagement and adherence to the digital components of blended interventions for mental health. Fourth, given the promising potential of harnessing digital technologies for bridging the gap in mental healthcare in low resource settings [45], future research should examine WA in digital mental health interventions in non-western cultures and settings.

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Page 35 of 51

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773 FOOTNOTES

774 Author contribution

Asmae Doukani (AD) developed the concept of the work. Patient involvement shaped the focus of the research. AD led all aspects of patient involvement. Arlinda-Cerga Pashoja (ACP) and Shumaila Usmani assisted with the patient involvement focus groups. The design and analysis of the patient involvement focus groups was contributed to by Sarah Smith (SS), Jesus Montero-Marin (JMM), Caroline free (CF) and Ricardo Araya (AR). AD, CF, SS significantly contributed to the design of the qualitative participant interview and Nicki Thorogood provided guidance in respect to the methodology. AD led all aspects of data collection, analysis and interpretation. CF and Daniel Michaelson (DM) analysed a portion of the data independently. The iterative development of the conceptual framework was led by AD, overseen by DM and Ritsuko Kakuma (RK), and contributed to by CF, RA, and ACP. AD prepared all iterations of the manuscript, with significant contributions from RK, CF, DM, RA, JMM, SS and ACP.

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guidance on the participant qualitative interviews methodology and to Shumaila Usmani who
helped facilitate and transcribe the patient involvement focus group interviews. Jesus MonteroMarin is supported by the Wellcome Trust Grant (104908/Z/14/Z).

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603098.

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Conflict of interest: All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi disclosure.pdf and declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

Ethical approval: The project was approved by the Health Research Authority's Ethics Committee on 17th April 2015 (REC reference: 15/LO/0511) and the London School of Hygiene and Tropical Medicine Research Ethics Committee on 9th June 2015 (Ethics Ref: 9409).

Transparency declaration: The lead author (AD) affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

Data sharing statement: Data available upon reasonable request.

¹ The use of the 'alliance' as a singular, broadly refers to the client-therapist alliance, and not to a specific variation (e.g. therapeutic alliance, working alliance, helping alliance etc.,) which while at times used interchangeably, have distinct theoretical underpinnings.

ⁱⁱ PPI was enlisted before the focus of the project was finalised, therefore people with a range of lived experiences were invited to be involved.

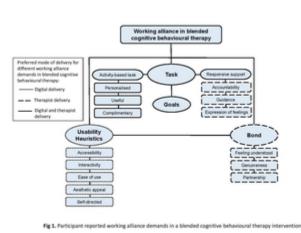
ⁱⁱⁱ The PWP workforce provide short-term, evidenced-based treatment in line with National Institute for Health and Care Excellence (NICE) guidance, to help people manage symptoms of mild to moderate depression and/or anxiety.

^{iv} A participant who was allocated to the treatment as usual group was erroneously put forward as a suitable b-CBT candidate. This case was discovered during the interview, and corroborated with the E-compared trial manager after the interview. Data for this participant was not analysed.

^v The aim of the study was to explore the relevance of the working alliance and to adapt the theory for the context of a b-CBT intervention. During the data analysis phase, it was decided that emerging data that fitted with Bordin's[9,10] conceptualisation, would be labelled according to existing categories (bond, goal, task). However, while the labels broadly fit with Bordin's [9,10] key categories, these labels are specific to b-CBT WA demands.

vⁱ WAI-SF-C scores are unavailable for participants who did not complete their online 3 month follow-up assessments on the E-Compared trial.

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COREQ (COnsolidated criteria for REporting Qualitative research) Checklist

A checklist of items that should be included in reports of qualitative research. You must report the page number in your manuscript

where you consider each of the items listed in this checklist. If you have not included this information, either revise your manuscript

accordingly before submitting or note N/A.

Торіс	Item No.	Guide Questions/Description	Reported Page N
Domain 1: Research team			
and reflexivity			
Personal characteristics			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	
Occupation	3	What was their occupation at the time of the study?	
Gender	4	Was the researcher male or female?	
Experience and training	5	What experience or training did the researcher have?	
Relationship with			
participants			
Relationship established	6	Was a relationship established prior to study commencement?	
Participant knowledge of	7	What did the participants know about the researcher? e.g. personal	
the interviewer		goals, reasons for doing the research	
Interviewer characteristics	8	What characteristics were reported about the inter viewer/facilitator?	
		e.g. Bias, assumptions, reasons and interests in the research topic	
Domain 2: Study design			
Theoretical framework			
Methodological orientation	9	What methodological orientation was stated to underpin the study? e.g.	
and Theory		grounded theory, discourse analysis, ethnography, phenomenology,	
		content analysis	
Participant selection			
Sampling	10	How were participants selected? e.g. purposive, convenience,	
		consecutive, snowball	
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail,	
		email	
Sample size	12	How many participants were in the study?	
Non-participation	13	How many people refused to participate or dropped out? Reasons?	
Setting			
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	
Presence of non-	15	Was anyone else present besides the participants and researchers?	1
participants			
Description of sample	16	What are the important characteristics of the sample? e.g. demographic	
		data, date	
Data collection			
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot	
		tested?	
Repeat interviews	18	Were repeat inter views carried out? If yes, how many?	
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	
Field notes	20	Were field notes made during and/or after the inter view or focus group?	1
Duration	21	What was the duration of the inter views or focus group?	1
Data saturation	22	Was data saturation discussed?	
Transcripts returned	23	Were transcripts returned to participants for comment and/or	

Торіс	Item No.	Guide Questions/Description	Reported or
		correction?	Page No.
Demain 2. enalysis and		corrections	
Domain 3: analysis and			
findings			
Data analysis			1
Number of data coders	24	How many data coders coded the data?	
Description of the coding	25	Did authors provide a description of the coding tree?	
tree			
Derivation of themes	26	Were themes identified in advance or derived from the data?	
Software	27	What software, if applicable, was used to manage the data?	
Participant checking	28	Did participants provide feedback on the findings?	
Reporting			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings?	
		Was each quotation identified? e.g. participant number	
Data and findings consistent	30	Was there consistency between the data presented and the findings?	
Clarity of major themes	31	Were major themes clearly presented in the findings?	
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	
Developed from: Tong A Sain	shury P. Cra	ig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-ite	em checklist

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Reporting checklist for qualitative study.

Based on the SRQR guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

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O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. Standards for reporting qualitative research: a synthesis of recommendations. Acad Med. 2014;89(9):1245-1251.

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		Reporting Item	Numb
Title			
	<u>#1</u>	Concise description of the nature and topic of the study identifying the study as qualitative or indicating the approach (e.g. ethnography, grounded theory) or data collection methods (e.g. interview, focus group) is recommended	Pag Numb
Abstract			
	<u>#2</u>	Summary of the key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results and conclusions	3
Introduction			
Problem formulation	<u>#3</u>	Description and signifcance of the problem / phenomenon studied: review of relevant theory and empirical work; problem statement	6
For p	eer review	only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	

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Purpose of the study and specific objectives or

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Purpose or research

<u>#4</u>

question		questions	
Methods			
Qualitative approach ar research paradigm	nd <u>#5</u>	Qualitative approach (e.g. ethnography, grounded theory, case study, phenomenolgy, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g. postpositivist, constructivist / interpretivist) is also recommended; rationale. The rationale should briefly discuss the justification for choosing that theory, approach, method or technique rather than other options available; the assumptions and limitations implicit in those choices and how those choices influence study conclusions and transferability. As appropriate the rationale for several items might be discussed together.	8-1
Researcher characteristics and reflexivity	<u>#6</u>	Researchers' characteristics that may influence the research, including personal attributes, qualifications / experience, relationship with participants, assumptions and / or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results and / or transferability	
Context	<u>#7</u>	Setting / site and salient contextual factors; rationale	12-1
Sampling strategy	<u>#8</u>	How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g. sampling saturation); rationale	
Ethical issues pertainin to human subjects	g <u>#9</u>	Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues	
Data collection method	s <u>#10</u>	Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative	12-1
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Page 5	i1 of 51		BMJ Open	Π
1 2 3 4			process, triangulation of sources / methods, and modification of procedures in response to evolving study findings; rationale	BMJ Open: first published 8-7, 12- 13
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Toward a conceptual framework of the working alliance in a blended low-intensity cognitive behavioural therapy intervention for depression in primary mental health care: A qualitative study

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Complete List of Authors:	Doukani, Asmae; London School of Hygiene and Tropical Medicine, Faculty of Epidemiology and Population Health Free, Caroline; London School of Hygiene and Tropical Medicine, Faculty of Epidemiology and Population Health Michelson, Daniel ; University of Sussex, School of Psychology Araya, Ricardo; King's College London, Health Service and Population Research Department Montero-Marin, J; Oxford University, Department of Psychiatry Smith, Sarah; London School of Hygiene & Tropical Medicine, Health Services Research and Policy Cerga-Pashoja, Arlinda; London School of Hygiene and Tropical Medicine, Faculty of Epidemiology and Population Health Kakuma, Ritsuko ; London School of Hygiene and Tropical Medicine, Faculty of Epidemiology and Population Health
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5	Corresponding author
6	Asmae Doukani, Research Fellow
7	Faculty of Epidemiology and Population Health, London School of Hygiene and Tropical
8	Medicine, Keppel Street, London, WC1E 7HT, United Kingdom.
9	Email: <u>Asmae.Doukani@lshtm.ac.uk</u>
10	Telephone: +44(0)207 927 2462
11	
12	Co-authors
12 13	Co-authors Caroline Free, Professor in Primary Care and Epidemiology
13	Caroline Free, Professor in Primary Care and Epidemiology
13 14	Caroline Free, Professor in Primary Care and Epidemiology Faculty of Epidemiology and Population Health, London School of Hygiene and Tropical
13 14 15	Caroline Free, Professor in Primary Care and Epidemiology Faculty of Epidemiology and Population Health, London School of Hygiene and Tropical
13 14 15 16	Caroline Free, Professor in Primary Care and Epidemiology Faculty of Epidemiology and Population Health, London School of Hygiene and Tropical Medicine Keppel Street, London, United Kingdom (Caroline.Free@lshtm.ac.uk)
13 14 15 16 17	Caroline Free, Professor in Primary Care and Epidemiology Faculty of Epidemiology and Population Health, London School of Hygiene and Tropical Medicine Keppel Street, London, United Kingdom (Caroline.Free@lshtm.ac.uk) Daniel Michelson, Senior Lecturer in Clinical Psychology
13 14 15 16 17 18	Caroline Free, Professor in Primary Care and Epidemiology Faculty of Epidemiology and Population Health, London School of Hygiene and Tropical Medicine Keppel Street, London, United Kingdom (Caroline.Free@lshtm.ac.uk) Daniel Michelson, Senior Lecturer in Clinical Psychology School of Psychology, University of Sussex, Pevensey Building, Falmer, Brighton, United

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3 4	22	Health Service and Population Research Department, King's College London, De Crespigny
5 6	23	Park, London, SE5 8AF, United Kingdom. (Ricardo.Araya@lshtm.ac.uk)
7 8 9	24	
10 11	25	Jesus Montero-Marin, Senior Postdoc Researcher
12 13 14	26	Department of Psychiatry, University of Oxford, Warneford Hospital, OX3 7JX Oxford,
15 16	27	United Kingdom (jesus.monteromarin@psych.ox.ac.uk)
17 18 19	28	
20 21	29	Sarah Smith, Associate Professor in Psychology
22 23	30	Department of Health Services Research and Policy, London School of Hygiene and Tropica
24 25	31	Medicine, Keppel Street, London, United Kingdom. (Sarah.Smith@lshtm.ac.uk)
26 27 28	32	
29 30	33	Arlinda Cerga Pashoja, Research Fellow
31 32	34	Faculty of Epidemiology and Population Health London School of Hygiene and Tropical
33 34 35	35	Medicine, Keppel Street, London, United Kingdom. (Arlinda.Cerga-Pashoja@lshtm.ac.uk)
36 37	36	
38 39	37	Ritsuko Kakuma, Associate Professor
40 41	38	Faculty of Epidemiology and Population Health London School of Hygiene and Tropical
42 43 44	39	Medicine, Keppel Street, London, United Kingdom. (Ritsuko.Kakuma@lshtm.ac.uk)
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Department of Psychiatry, University of Oxford, Warneford Hospital, OX3 7JX Oxford,	
United Kingdom (jesus.monteromarin@psych.ox.ac.uk)	Protec
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42 Abstract

Objectives: To examine and adapt a conceptual framework of the working alliance (WA) in
the context of a low-intensity blended (psychological wellbeing practitioner (PWP) plus
computerised program) cognitive behavioural therapy intervention (b-CBT) for depression.

46 Design: Patient involvement was enlisted to collaboratively shape the design of the project 47 from the onset, before data collection. In-depth semi-structured interviews were carried out 48 with participants who experienced b-CBT as part of the E-compared trial. A thematic analysis 49 was conducted using a constant comparative method informed by grounded theory.

50 Setting: Recruitment was carried out in four psychological primary care services across the
51 UK.

Participants: Nineteen trial participants with Major Depressive Disorder who completed at
least one computerised programme and face-to-face session with a PWP in the b-CBT arm,
were recruited to the study.

Results: Qualitative interviews that were guided by WA theory and patient involvement, revealed four themes: (1) A healthcare provider (PWP and programme) with good interpersonal competencies for building a working relationship with the client ('Bond'); (2) collaborative efforts between the client and the provider to appropriately identify what the client hopes to achieve through therapy ('Goals'); (3) the selection of acceptable therapeutic activities that address client goals and the availability of responsive support ('Task'); and (4) the promotion of active engagement and autonomous problem solving ('Usability heuristics'). Participants described how the PWP and computerised-program uniquely and collectively contributed to different WA needs.

64 Conclusions: This study is the first to offer a preliminary conceptual framework of WA in b65 CBT for depression, and how such demands can be addressed through blended PWP-program

delivery. These findings can be used to promote WA in technological design and clinical
practice, thereby promoting engagement to b-CBT interventions, and the effective deployment
of practitioner and program resources.

69 Trial registration: E-Compared Trial, ISRCTN registry, ISRCTN12388725. Registered on 20
70 March 2015.

Keywords: Working alliance, blended psychological interventions, cognitive behavioural blic invo. therapy and patient and public involvement.

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Strengths and limitations of the study

Article summary

- Patient involvement enabled the project aims to be grounded on the needs and interests of people who have experienced mental health service-use, in order to enhance the application of the findings.
- Bordin's theory was specifically selected to examine the working alliance (WA) in blended cognitive behavioural therapy, due to the theory's comprehensive description, pan-theoretical nature, and openness to adaptation to accommodate different therapeutic formats.
- The studies' sample is limited to 19 individuals with a primary diagnosis of mildto-moderate depression, mostly reporting moderate to high WA and were largely male, British white and university educated individuals, thereby restricting the generalisability of our findings.
- Exposure to only one type of digital program, may have influenced participants' experience of WA (e.g. a computerised platform that doesn't work adequately might generate more data on the importance of 'ease of use', than one that does), limiting the breadth of data collected on WA.
- Efforts were made to strengthen the conceptual framework through interview topic guides which were guided by Bordin's WA theory, patient involvement input, and a data analysis approach which avoided surface level themes, specific to technological design.

78 INTRODUCTION

Mental health conditions impact one in six people in Europe, resulting in an estimated economic burden of over €600 billion.[1] The treatment gap in the region remains high with 35-50% of people experiencing mental health concerns not accessing treatment.[1] The wide disparity between mental health care needs and access to services has prompted calls for the strategic deployment of technology to facilitate and expand access to mental health services at a lower cost.[2,3] In the past decade, an increasing number of studies have investigated the efficacy of computerised cognitive behavioural therapy (c-CBT), a type of digital intervention that delivers CBT via interactive presentation features.[4] The implementation of c-CBT is generally either unguided (led by a computerised program with no external support), guided (led by a computerised programme and typically supported by a non-specialist facilitator) or blended (led by a therapist, incorporating a c-CBT programme, or led by a c-CBT program and supported by a therapist), with the latter approach offering the highest level of human support.[4,5]

The evidence for c-CBT has demonstrated equal benefits to face-to-face CBT for a range of mental health conditions.[4] However, these findings largely hold true when digital psychotherapies are guided by a human facilitator. Higher support from a therapist or another human facilitator appears to be related with better adherence and clinical outcomes.[6] The effects of human support on engagement with c-CBT raises important questions about mechanisms that support positive change in c-CBT. This has led scholars to consider the applicability of established mechanisms of change derived from conventional psychotherapies, to 'blended' formats. Particular interest has centred on the construct of the client-therapist allianceⁱ (therapeutic, working etc.).[7,8] While the concept of the alliance has taken root in a

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number of psychotherapeutic approaches, Edward Bordin[9] drew on their commonalities to
formulate a pan-theoretical theory called the working alliance (WA) originally defined as:

"a formation between the client seeking change and the therapist offering to act as a change agent that incorporated a mutual understanding and agreement about change goals and the necessary tasks to move forward these goals along with the establishment of bonds to maintain the partners' work".[9,10] (pg. 13)

Here, the 'task' refers to an agreed-upon contract that specifies the activities used to work on the client's goals. 'Goals' entails the exploration and review of what the client wants to achieve in therapy, while the 'bond' relates to the perceived compatibility between the client and the therapist, and the partnership that stems from shared activities.[9,10] Central to Bordin's[9,10] conceptualisation, is the collaboration and consensus between the therapist and the client, in order to promote meaningful engagement in therapy.

The alliance has consistently been found to predict positive therapeutic outcomes. A keystone meta-analytic review found that the therapeutic alliance accounted for more variance (30%) than the therapeutic technique (15%) and therapy expectancy (15%).[11] This allianceoutcome relationship finding, was mirrored in recent meta-analyses, one of 191 varied therapeutic studies (r = .28 [95% CI: .25 to .30]),[12] and another focusing on CBT interventions for depression (r = .26 [95% CI: .19 to .32]).[13]

A growing body of literature on the alliance in internet-based psychological interventions indicate that the quality of the alliance in guided psychotherapy programs and b-CBT may be equal to or better than traditional formats of face-to-face therapy.[14–16] There is also evidence to suggest that the client reported alliance in guided c-CBT is directly associated with treatment outcome.[17,18] However, some literature appears to suggest that c-CBT may place different demands on the alliance. A narrative review evaluating WA in supported c-CBT found that

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while significant associations were found between the task and goals sub-scales of WA and
treatment outcome, none were found for the bond subscale.[18] Qualitative research on the
alliance in unguided mental health interventions also indicate that cCBT may offer additional
alliance benefits such as higher control and autonomy.[19,20]

Taken together, these findings underscore the importance of developing a guiding framework for understanding the nature of WA in b-CBT, amidst a gradual movement towards shared mental health care delivery between human practitioners and digital technology.[21] Our study therefore aims to examine the WA demands through patient involvement and participant qualitative interviews, to adapt Bordin's[9,10] conceptualisation of WA for a b-CBT intervention for depression.[22]

136 METHOD

Patient and public involvement

Patient advisors were enlisted at a pre-research data collection stage to collaboratively examine WA in a digital CBT program without human support. Patient advisors were not involved in the recruitment of participants or of conducting the study. Patient involvement included eleven advisors with experience of mental health service use, predominantly for mild-moderate depression (n=7), but also for anxiety (n=1) and severe mental health conditions (n=3)ⁱⁱ. Advisors attended two meetings in the summer of 2015. The first meeting consisted of a comprehensive pre-involvement preparation briefing, to provide advisors with the knowledge and skills that would enable optimal conditions to aid their role.[23] Advisors were also provided with access to a c-CBT for depression program called Moodbuster (program used on the E-Compared trial),[24] which they were encouraged to test and review in their own time, to provide context for discussion.[23] Advisors voluntarily tested all components of the Moodbuster intervention between meetings. In the second meeting, advisors were split into

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three small focus group discussion interviews, to facilitate the sharing of personal experiences and enable a higher level of opportunities to participate.[25] Discussions attempted to address three objectives, including: (i) is WA, as defined by Bordin[9,10] relevant in the context of a digital program intervention? (ii) What are the intrinsic WA demands between the client and the digital provider? and (iii) Can digital delivery offer new ways of building WA, above and beyond Bordin's[9,10] bond, goals and task? The three focus group discussions were audio-recorded using an Olympus digital voice recorder WS-852, transcribed, and analysed to identify thematic patterns and themes. Patient involvement contribution was reported in line with version 2 of the Guidance for Reporting Involvement of Patients and the Public Short Form (GRIPP2-SF).[26] Patient advisors were thanked for their contribution after their involvement and also in the acknowledgements of this paper. The results of the study will be disseminated via a lay summary of the research, which will be supplemented with a peer-reviewed publication.

Patient involvement was instrumental in shaping the focus of the study and in guiding participant interviews in three different ways: First, patient involvement input suggested that Bordin's [9,10] WA as a function of enhancing engagement, was both relevant and important in the context of a digital psychological intervention. Second, the focus of the planned participant interviews changed from exploring WA within a computerised CBT (c-CBT) intervention without human support, to exploring the shared therapist-program format of CBT, as advisors unanimously suggested that some WA needs (especially bond and elements of support) could not be satisfied without human facilitation. Third, we set out to extend Bordin's [9,10] WA theory as patient involvement suggested that the c-CBT program could lead to additional alliance building and maintenance benefits.

3 4	175	Design
5	176	A qualitative methodology design was used to gain an in-depth understanding of participants'
7 3	177	experience of WA in b-CBT on the E-compared trial.[24] E-compared is a non-inferiority,
9 10 11	178	pragmatic trial that evaluated the cost effectiveness of b-CBT for depression, when compared
12 13	179	to usual care, across eight countries in the European region.[24] Potential participants from the
14 15	180	UK were referred from primary care services by clinical staff, if they scored 4 points or higher
16 17	181	on the Patient Health Questionnaire-9,[27] and if they were interested in receiving b-CBT for
18 19 20	182	depression. The b-CBT intervention consisted of 11 blended low-intensity CBT sessions, six
20 21 22	183	with a low-intensity psychological wellbeing practitioner (PWP ⁱⁱⁱ) (average duration of 30
23 24	184	minutes) and a least five at home via a synchronised computerised platform and mobile-
25 26	185	application called Moodbuster. The treatment course spanned across 11 weeks. There were
27 28 29	186	four mandatory core modules of CBT on the digital platform (psychological education,
30 31	187	behavioural activation, cognitive restructuring, and relapse prevention) and two optional
32 33	188	modules (physical exercise and problem solving) that were completed autonomously at home.
34 35 26	189	The low-intensity PWP in the clinic encouraged participants to use the computerised
36 37 38	190	programme in different ways. The PWP could introduce modules, review if the client had
39 40	191	completed modules, or guide the client on the use of specific modules). Face-to-face sessions
41 42 42	192	in the clinic were alternated with Moodbuster sessions away from the clinic, however there was
43 44 45	193	flexibility in the sequence of the delivery mode and the order in which the modules were
46 47	194	completed, including opportunities for the PWP to use bespoke tasks. Additional information
48 49	195	about the trial and the b-CBT intervention can be accessed from the trial protocol by Kleiboer
50 51 52 53	196	and colleagues.[24]

Participants

E-Compared participants from the UK were invited to take part in qualitative interviews. Trial participants aged 18 years or older with a clinical diagnosis of Major Depressive Disorder

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(MDD), were enrolled in the study.[24] People with substance abuse, suicidal tendencies, other severe psychiatric disorders, cognitive disability or people who had insufficient knowledge of English were excluded. Psychiatric diagnoses were confirmed by the MINI International Neuropsychiatric Interview (M.I.N.I) version 5.0.[28] E-Compared trial[24] participants who: (a) provided written consent to the qualitative interviews when they enrolled on the trial (n=101); (b) were randomised to the b-CBT arm (n=49); and (c) had completed at least one computerised module and face-to-face session (n=42) were purposively sampled to be representative of the b-CBT arm, in relation to their sex, age, and recruitment site.[29] Altogether, 26 out of 42 people were invited to take part in the qualitative study, with 19 reconsenting to participate. Reasons for non-consent included scheduling conflicts (n=2) non-response to invitation (n=4), and change in eligibility status due to erroneous information about arm allocation $(n=1^{iv})$.

Procedure

E-compared participants were invited to take part in face-to-face individual semi-structured qualitative interviews, at least 2 weeks after they completed their course of therapy on the trial. This was to provide participants with enough time to reflect on their experience of the b-CBT intervention. Potential participants were invited to take part in interviews about their experience of b-CBT, and were emailed a patient information sheet following their initial correspondence with the research team. Participants were provided with at least 48 hours to read and consolidate the information, before they were followed up and booked in for a qualitative interview at an acceptable time and place. Written consent for their participation, as well as audio recording of the interview, was sought again prior to starting their interviews and were reminded of their right to withdraw at any time and without giving a reason. Data collection took place until saturation was reached.[29] The study adopted Corbin and Strauss's definition of saturation, which is described as the point where further data collection becomes 'counter-productive',

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and where 'new' themes do not add anything to the overall narrative of the story.[29] Saturation
was monitored through writing memos after each interview, in which information on both key
and novel emerging themes from the interview were recorded.[29]

The project was approved by the Health Research Authority's Ethics Committee on 17th April
2015 (REC reference: 15/LO/0511) and the London School of Hygiene and Tropical Medicine
Research Ethics Committee on 9th June 2015 (Ethics Ref: 9409).

231 Measures

Self-reported WA and symptoms of depression, collected on the E-Compared trial[24] were reported to further describe participant characteristics (in addition to sociodemographic data) and to provide insights on WA and the level of depression experienced by the participants on the study. Self-reported WA was assessed through the Working Alliance Inventory Short Form - Client (WAI-SF-C).[30] Scores for the 12 items on WAI-SF-C range between 12- 60. Scores were divided into 3 groups to produce a low-range (12-28), medium-range (29-44), and high-range (45-60) to indicate the level of WA reported by each participant. Higher scores indicate better WA. Self-reported depression was assessed through the Patient Health Questionnaire-9 (PHQ-9).[27] Scores for the 9 items on the PHQ-9 range between 0-27. Higher scores indicate more severe symptoms. Data was collected during the trial's three months follow-up assessments.[24]

Guiding framework

Our study adopted Edward Bordin's[9,10] theory to examine WA in the context of b-CBT for three reasons. The first relates to the generalisable nature of the theory. While the concept of the alliance stemmed from psychodynamic theory in 1912, it has since been incorporated in various therapeutic approaches, leading to heterogeneity in the way the concept is defined.[12] In 1979, Bordin[9,10] attempted to unify the way the alliance is defined, by proposing a panEnseignement Superieur (ABES) . Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.

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theoretical conceptualisation[9] that drew on the key features of all therapeutic approaches.[12] Second, Bordin's [9,10] theory is operationalised as task focused, [12] and therefore offers a suitable fit for task-orientated psychological approaches such as CBT.[31] Third, the theory is open to adaptation. Bordin[9,10] suggested that while a pan-theoretical approach allowed the basic measurement of the bond, goals and task to produce beneficial therapeutic change, he also suggested that the ideal alliance *profile* is likely to be different across therapeutic approaches and interventions.[9,10,12]

Data collection

Data collection took place between October 2016 and July 2017 across four primary care mental health services in the UK. Qualitative interviews were adopted to enable a detailed examination of the participant's personal experiences and perspectives of WA within the context of their experience of receiving b-CBT. The study predominately included a deductive approach to exploring WA in b-CBT based on Bordin's [9,10] theoretical framework, while remaining open to novel or unexpected inductive new findings. On average, participant interviews lasted around 47 minutes. Interviews were conducted in a confidential setting within a university campus or the health service which the participant was recruited from. All interviews were audio-recorded using an Olympus digital voice recorder WS-852 and transcribed to produce orthographic verbal verbatim. AD (female) conducted the qualitative interviews, was a PhD Candidate with experience of conducting and analysing qualitative data. Semi-structured interviews with a conversational technique were used to achieve a balance between the need for consistency of questioning across participants, and the ability to explore topics that are important to the participant. During interviews there was also scope to allow topics covered to evolve iteratively based on the emerging data. [29,32] The development of an interview topic guide was supported by patient involvement input and guided by the WA

Page 15 of 51

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theory[9,10]. The initial topic guide was used to suggest topics of discussion, and not as a definitive framework to limit conversations. As the data collection progressed, the topic guides evolved iteratively based on emerging themes. Subsequent interviews were therefore influenced by interviews that previously took place, providing opportunities to validate and refute interpretations.[29]

280 Data analysis

A preliminary data analysis took place alongside early interviews, allowing subsequent interviews to progress iteratively.[29] Memos were written after each interview, to aid the preliminary analysis and iterative adaptation of the topic guide and to propose possible relationships between codes. Thematic analysis was adopted due to the theoretical flexibility, as well as the 'thick descriptions' afforded by the approach.[33] The data analysis incorporated a constant comparative method from grounded theory, to enable the analyst to search for new theoretical models that are grounded in empirical data, and to enhance the trustworthiness of data.[29]

The lead analyst (AD) commenced the data analysis by reading through the transcripts, while listening to the audio recording and reading the corresponding memos. The analyst then actively re-read the data, searching for meaning, and noted down initial concepts. Data was coded line-by-line. Codes were generated by searching for interesting features across the entire dataset and collating data relevant to each code segments. The emerging codes were clustered into categories and labelled thematically. Once the data was initially coded and collated, the analyst commenced searching for themes that were compatible with Bordin's [9,10] WA theory and patient involvement input, while also searching for novel alliance concepts. Themes were located at a latent level, to delve beyond the semantic content of the data, to identify and

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examine underlying ideas, assumptions, conceptualisation and ideologies that theorise semantic content of the data.[33] The initial codes were gradually merged into broader categories through comparison across transcripts, to identify overarching themes. The themes were then reviewed to ensure that the codes cohere together meaningfully, while maintaining a clear and identifiable distinction with no overlap between the themes. Finally, the themes were reviewed to consider their relationship to the overall thematic map. Once a thematic 'map' was identified, the findings were developed into a conceptual framework of WA in b-CBT.[33] Two other members of the research team (CF and DM), who are highly familiar with qualitative methodologies and Bordin's[9,10] WA theory, read through 20% of all transcripts and reviewed all supporting quotes across all phases of the analysis, so that close to half of the transcripts were reviewed. Discrepancies were discussed and reconciled. The final framework was discussed and revised over eight meetings. The entire coding process was performed using the NVivo 11 data analysis software package. Supporting quotes were anonymised to ensure that participants and their PWP could not be identified. To ensure the final conceptual framework accurately reflected WA, a 'therapeutic process',

was not confounded with early manifestations of 'treatment outcomes' we defined "therapeutic processes" relevant to WA, and the 'treatment outcomes' associated with CBT.[30] 'Therapeutic process' was defined as "actions, experiences, and relatedness of the client and the therapist in therapy sessions...". [34] We a-priori extended the use of the term 'therapy session' to include face-to-face and digital delivery in the context of blended therapy. Horvath and colleagues[30] noted three ways of defining the outcome in psychotherapy including: (a) the core value attributed to the outcome by the client, (b) the importance of the outcome in the theoretical framework of the therapist, and (c) the utility of the outcome (e.g. the technique) to promote other outcomes that are valued. We defined outcome in relation to definitions b and c to enable a standardised definition that does not vary from client-to-client (i.e., definition a).

Page 17 of 51

BMJ Open

We a-priori define the outcomes of CBT as the alleviation of distress *(b)* through helping the client to develop more adaptive cognitions and behaviours *(c)*.[31] The final conceptual framework was reviewed in light of the aforementioned definitions by members of the research team. Themes and sub-themes that were judged to correspond with the definition of 'treatment outcome' were removed. We used the SRQR checklist when reporting our findings.[35]

RESULTS

Description of sample

An exploration of WA in b-CBT was undertaken through 19 qualitative interviews with participants who experienced b-CBT in the treatment arm of the E-Compared trial[24]. Participants were aged between 19-67 years (Mean=34.47 years, SD=14.44 years), were largely male (n=13), white British or white other (n=12), and university educated (n=12) (full sample characteristics are presented in Table 1). All interviews were conducted face-to-face apart from one, which was completed by phone. Saturation appeared to be reached by the 16th interview. Another three interviews were carried out to ensure that the selected saturation cut-off point had been accurately identified and to further validate interpretations. Tables 2-4 show that the main themes were endorsed by 89% - 100% of participants, indicating that the selected saturation cut-off point was sufficient.

Table 1. Sample characteristics of participants who took part in the qualitative interviews (n=19)

Characteristics	Mean (SD) or Percentage (<i>n</i>)
Age in years	34.47 (14.44) range 19- 67 years
Gender (male)	69% (13)
Marital status	
Divorced	5% (1)

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Living together	11% (2)		
Single	63 % (12)		
Married	21% (4)		
Highest educational level completed			
Secondary School, equivalent	11% (2)		
Colleague, equivalent	26% (5)		
University degree or higher	63% (12)		
Ethnicity			
British white or white other	63.1% (12)		
Black/African/ Caribbean / Black British	5.3% (1)		
Asian or Asian British (Any other Asian)	21% (4)		
Mixed or Multiple Ethnic Group	5.3% (1)		
Other	5.3% (1)		
Intervention completion level ^a	0.070 (1)		
Completed course of b-CBT	63.2% (12)		
Incomplete course of b-CBT	36.8% (7)		
WAI-SF-Pb	46.29 (SD=10.21), score range 27-60 (17)		
High WAI-SF-P	score range 47-60 (10)		
Medium WAI-SF-P	score range 31-41 (6)		
Low WAI-SF-P	score 27 (1)		
No score	(4)		
PHQ-9°	7.8 (6.87), score range 1-22 (n=18)		

^a Intervention completion level: A complete course of b-CBT refers to the completion of four mandatory Moodbuster modules (psychological education, behavioural activation, cognitive restructuring and relapse prevention), while an incomplete course of b-CBT course refers to the non-completion of the four mandatory Moodbuster modules.

^b WAI-SF: Working Alliance Inventory Short Form. Four participants did not provide data for this questionnaire during their 3 month follow-up assessment.

°PHQ-9: Patient Health Questionnaire-9.

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Conceptual framework of WA in b-CBT 343

A thematic analysis with a constant comparative method[33] revealed multifaceted WA 344 demands which show that the work of building WA in b-CBT involved a symbiotic effort by 345 the PWP and the digital program, to actively engage the client to meaningful therapeutic 346 activities and to promote self-discovery and commitment to the intervention. Such demands 347 348 can be grouped into four overarching WA themes, (1)'bond', (2)'task', (3)'goals' (in line with Bordin's [9,10] WA theory categories^v) and (4) 'usability heuristics' (a newly emerging theme) 349 (See Fig. 1 for a summary of the main themes and sub-themes). 350

Theme 1: Bond 351

The 'bond' is defined as a set of mental health care provider (including both the PWP and 352 computerised program) competencies that enable a working relationship to be established and 353 maintained with a client. Participants unanimously reported that a human therapist was the 354 most important facilitator for building the bond in a b-CBT context. This was because 355 participants valued qualities of 'humanity', and 'responsiveness' attributed to a human 356 therapist. Through a process in which participants appeared to compare and contrast the 357 358 strengths of the digital program with the PWP, most participants questioned the 'meaningfulness' of interacting with a digital platform that was incapable of understanding or 359 responding to a client's needs as demonstrated by the following quote: 360

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"an app is like a machine, it's not personal at all. I think it's good to have some element[s] of talking to a human about this kind of thing because I think you want reassurance as well, which you wouldn't get from an app and if you did it would just be responses built in".

(P8, low-range Working Alliance Inventory Short Form – Client (WAI-SF-C)) 366

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> Data from participant interviews revealed three broad PWP attributes considered to be important for the bond building process, namely the mental health providers' ability to; effectively demonstrate their understanding of their client's struggles and needs (sub-theme 1.1); convey that they are genuine in their endeavours towards the client (sub-theme 1.2); and forge a working partnership founded on friendliness, feeling cared for, empathy and trust (sub-theme 1.3) (see Table 2 for sub-theme descriptions and supporting quotes). Some participants elaborated on these concepts further to unearth granular insights of what it means to be in the presence of a PWP. Visually observing a PWP's non-verbal cues was reported to be especially important for gauging abstract relational concepts such as empathic understanding (sub-theme 1.1), and genuineness (sub-theme 1.2). The recognition of positive non-verbal cues appeared to increase congruence between the PWP and the client (sub-theme 1.3) throughout the course of therapy:

"[During telephone therapy] he was like "mm hm, go on ...so how do you feel?" I
can't see his face. I don't know what he was thinking. I can't feel him. But during
face-to-face [sessions] I think when I talk about something I can notice, his or her like
facial expression. I know he's listening ...That make[s] me feel like talk[ing] more".
(P14, WAI-SF-C score not available^{vi})

 Table 2. Theme 1, bond sub-theme descriptions and supporting quotes

Theme, percentage of sample endorsed	Supporting quotes	
(<i>n</i>) and description		
THEME 1: Bond, 89%, (17)		
1.1 Feeling understood, 74% (14)	P12, high-range WAI-SF-C score:	
The PWP's ability to make the client feel	"My therapist did make a real effort to try and get to know me, try to	

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3 4		closely listen to the client, comprehend	did, rather than just assuming this is what you need without taking	
5		what is being said and demonstrate	into account maybe what I as a person, personally needed".	
6 7		empathic awareness and insight into the		
8		client's concerns.		
9 10				
10 11				
12		1. 2 Genuineness, 32% (6)	P9, low WAI-SF-C score:	
13 14		The PWP's efforts to help the client, that	"To be honest, I kind of felt like she [PWP] was very fakeEvery time	
15 16		are perceived as genuine and authentic, as	I'd say something there would be an, ahh, it just felt not genuine at all,	
10 17 18		opposed to procedural or routine.	that she was just saying it because she thought I felt down"	
19 20		1.3. Partnership, 74% (14)	P12, high-range WAI-SF-C score:	
21 22				
23			"I feel like she, as I said earlier, took the time to get to know me and	
24 25		achieve a working relationship that is akin	what I was currently doing, so it did feel like she kind of knew me	
26		to a friendship. Such a partnership is	on an individual level, rather than just being the patient."	
27 28		characterised by trust, feeling liked and		
29 30		feeling cared for.	6	
30 31		*WAI-SF-C: Working Alliance Inventory Short	Form- Client.	
32 33	386			
34	500			
35 36 37	387	Theme 2: Goals		
38 39	388	'Goals' refers to the collaborative work between the PWP, the client and the digital interface,		
40 41 42	389	to appropriately identify what the client hopes to achieve through therapy (68% of sample		
43 44	390	ile 'goals' emerged as a distinct factor, it also appears		
45 46 47				
48 49	392	tasks and maintaining the client's motiv	vation to work towards creating change.	
50 51 52	393	"The goal setting actually was something that I spoke to [the PWP] quite a bit about in		
53 54	394	the session [] I was then like "God well what are my goals? [] what, where am I		
55 56	395	exactly going?" (P5, higher-range WAI-SF-C score)		
57 58 59 60	396			

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397 Theme 3: Task

The 'task' refers to the careful selection and acceptability of the therapeutic activities prescribed to address the client's presenting symptoms ('activity-based task'), and the degree to which the support received by the healthcare provider on these activities is responsive ('responsive support').

The defining features of 'activity based-task' refers to the client's ability to work on tasks that are; personalised and acceptable for addressing the client's therapy goals (sub-theme 3.1); useful in promoting new learning, insights and reflection (sub-theme 3.2) and are complimentary across both modes of delivery (sub-theme 3.3). The defining features of 'responsive support' relate to the provider's (largely referring to the PWP's role) ability to appropriately respond to a range of clients' expressed and unexpressed needs to; maintain accountability (sub-theme 3.4); provide activity-based guidance (sub-theme 3.5); and have a safe-space for clients to express their feelings and emotions (sub-theme 3.6) (see Table 3 for sub-theme descriptions, and supporting quotes).

Table 3. Theme 2, task sub-theme descriptions and supporting quotes

Theme, percentage of sample endorsed (<i>n</i>)	Supporting quotes
and description	
THEME 3: Task 100%, (19)	
Activity-Based Task, 100% (19)	
3.1. Personalisation, 95% (18)	P12, high-range WAI-SF-C Score:
The level at which a client is able to tailor the	"I think it's a bit more personalised, because I would say
therapeutic task to their individual needs. A non-	whilst the E-Compared is good, it is still, it is to an extent
personalised digital intervention was reported to	generic, because it can't kind of know every single person
negatively impact engagement. The PWP in	that's watching the video, so whereas the therapists can kin
blended-therapy can play an important role in	of get an idea of you, your story, your journey, what's mayb
making a generic intervention (i.e. computerised	led you to kind of this maybe relapse, or for you to be feelin
CBT) as more personalised.	the way you are, and you can't maybe get that from a

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59 60 computer...Whereas if I'm hearing it from the person, I'm going to take a bit more notice, but then if I'm just hearing it from the computer, where it will say that to everyone watching the video"

3.2. Usefulness, 95% (18)

A useful task was defined as one that promotes new learning, reflection and is effective in creating desired change in the client's life.

P4, medium-range WAI-S-C score:

"But like the modules themselves, feelings-wise they were often quite helpful for clarifying stuff. Like I usually came out the other end feeling better or more kind of composed...it would kind of shape how I was seeing things. So like if I, you know learned about thought distortions, I'd kind of go in with that knowledge and be able to kind of talk about it..."

3.3. Complementary, 84% (16)

The ability to experience complementary tasks in face-to-face therapy and on the digital platform as continuous and cohesive, as opposed to stilted and disjoint. Knowing what to expect from the respective components of blended therapy was reported to help the client optimise the benefits sought from different components of therapy.

P16, medium working alliance:

"I was finding it really hard to leave the house so that whole thought of going to therapy was quite difficult in the very beginning, so it did take me a couple of sessions to really start talking to [therapist] and opening up but because I had this online support I found it easier to open up to [therapist] so maybe instead of you know, two sessions it would have taken four or five."

Responsive support Task, 100% (19)

3.4. Accountability, 79% (15)

The availability of a figure of authority that the client can (positively) feel responsible towards, as a means of garnering motivation to work on therapeutic activities. For the process of accountability to positively impact the client's motivation, a PWP is required to demonstrate their knowledge of the client's progress and provide feedback accordingly.

P19, medium-range WAI-S-C score:

"Oh right, OK. Well, to me, I saw it like homework, you've got to get it done otherwise you get into trouble, not that I would have got in trouble, but do you know what I mean, you're sort of motivated that way. And there is the other, the embarrassment of going in and saying 'oh yeah, I didn't do the modules' and then you feel really about that big and you know, someone's trying to help you and you haven't bothered to do your bit kind of thing. So that was a motivation in itself."

> 3.5. *Guidance, 89% (17)* The provision of guidance and reassurance on the therapeutic tasks by a **PWP**. The PWP's intuition, expertise, interpretation and foresight is especially considered as helpful in addressing salient issues that would not have otherwise been communicated by the client.

P10, high-range WAI-SF-C score:

"When you speak to your therapist, obviously she's had a lot of different scenarios with a lot of different people, she's got the experience and the know-how, and then obviously how I'm looking at it thinking the module's really working like this, she then says, "That's really brilliant, but to then add onto that and to support you, how about if you think about that?."

3.6. Expression of feelings 100% (19)

The client's expressed need to speak to another human being, in order to communicate issues that are pertinent to their treatment journey. In order for the client to optimally benefit, clients require the **PWP** to dedicate a sufficient amount of time for the activity. The amount of time required by each person appears to vary in relation to pre-therapy expectations and symptom severity.

P14, WAI-SF-C score unavailable:

"I think it's nice to have someone to talk to. It's kind of, I think it's important for me to express my feelings like in a private situation. Because sometimes I have, kind of I live with my partner but, you know, some[times], you can't talk to her."

WAI-SF-C: Working Alliance Inventory Short Form-Client.

The majority of participants noted the importance of experiencing the therapeutic activity as complementary across modes of delivery (sub-theme 3.3). Some participants elaborated that an initial step to achieving an effective symbiotic delivery was to provide the client with an understanding of how the PWP and digital delivery contributed towards their treatment both distinctively and collectively.

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Our findings also suggested that the ubiquity of c-CBT appeared to positively impact the clientPWP WA, through increased opportunities to reinforce what was learned through the digital
platform, with a PWP, and vice-versa, for instance:

- Well I think it gave you something to do over and above the face-to-face ... having the
 modules to go through, it reinforces what you're talking about face-to-face and makes
 it easier to understand. It's, that repetition thing isn't it where you learn by repetition
 basically and that's how I saw it working."
- 426 (P17, WAI-SF-C score not available)

428 Theme 4: Usability heuristics

The final alliance building theme identified is, 'usability heuristics', which refers to the process of predominantly using technology to promote active engagement, self-discovery and autonomous problem solving in b-CBT. This category is a novel component to Bordin's [9,10] theory. Features that enable 'usability heuristics' include ubiquitous digital technologies that; increase access and immediacy to the therapeutic task (sub-theme 4.1), appropriately respond to the client's input (sub-theme 4.2), are easy to use (sub-theme 4.3) have aesthetic appeal (sub-theme 4.4) and promotes self-directed therapy (sub-theme 4.5) (see Table 4 for sub-theme descriptions, and supporting quotes).

While PWP competencies emerged as the most important facilitator for building the alliance, almost all participants expressed that they preferred blended psychotherapy to face-to-face therapy alone. Some participants elaborated that their ability to access the intervention at any time or place of convenience (sub-themes 4.1) further bolstered their engagement to therapeutic activities (theme 2). Participants who reported a high technological affinity suggested that the appearance (sub-theme 4.4) and ease of use (sub-theme 4.3) of the interface impacted their

perceptions of the digital program's credibility and therefore, their desire to engage in treatmentactivities.

Almost all participants reported that the digital program provided them with the tools to initiate treatment independently (sub-theme 4.5), with some participants noting that they continued to use the digital program as a means of maintaining therapeutic gains once their therapy course had ended. Here, autonomous completion of the therapeutic task was described as a securebase that allowed clients to progressively explore self-directed therapy:

"it kind of reminds me of Winnicott and the Secure Base in Attachment theory in psychology, that you know, children become securely attached if they have a secure base in terms of the home and the parents that they can come back to, so they can go off and explore the world confidently in the knowledge that they can come back to security, and that, that helps them to develop - and it's kind of like that, I feel, with having that Moodbuster resource [digital program] there, that you can keep coming back to it ... there is a lot in there and you can keep going back and it's a sort of source of strength really".

40 458 (P10, higher-range WAI-SF-C score)
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459 Participants suggested that the blended approach prepared the client to engage in autonomous460 self-directed therapy, through a process of supervised autonomy.

Table 4: Theme 4, Usability heuristics, sub-theme descriptions and supporting quotes
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Theme, percentage of sample endorsed (<i>n</i>) and	Supporting quotes		
description			
THEME 4: Usability heuristics, 100% (19)			

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4.1. Accessibility, 95% (18)

The ability of a client to access the digital intervention at a time and place of convenience. Higher accessibility provides opportunities for the client to review and reflect on what has been learned at a deeper level.

P10, high-range WAI-SF-C score:

"Being on your own you know, in your own time and in your own safe place, your blanket, whatever you call it just allowed me personally just to open up and look at it, and then going from the start of the process to the end, ... thinking positively, looking at your behaviours, looking at adding little things in and then the exercise at the end, rewarding yourself for just achieving things what I felt at the time were trivial made everything different."

4.2. Interactivity, 63% (12)

An interactive digital program that is able to react to the clients input, to produce feedback. Interactive activities were perceived as more enjoyable, and promoted a degree of accountability.

4.3. Ease of use, 63% (12)

The ease of use of the digital interface is described as a well-functioning, intuitive, digital interface which enables optimal access to the therapeutic task.

P6, high working alliance:

"One thing immediately comes to mind, it has to be a bit more interactive I think. The client shall we say, as well I feel should be given more feedback, the results, you know when you're scoring yourself on those, what that's about you know, how do they interpret that score, when you're putting your mood in on the smartphone, what's that about you know, who's looking at that, who's interpreting that".

P2, high-range WAI-SF-C score:

"It was really nice, I thought it was really, well very well presented I would say, and everything was just there, like for easy viewing, so you didn't have to like go through like folders or like go deeper into the website, like it was just there, and you know, I could just easily click on what I needed to do and just follow the instructions set out on the exercises."

4.4. Aesthetic appeal, 21% (4)

The appearance or appeal of the digital interface is a factor that clients use to judge the credibility of the digital intervention and which could impact their engagement to the therapeutic task.

P13, medium-range WAI-SF-C score:

"Yeah, and actually it became quite a bit of work just keeping up with the calendar, sort of, I found it a bit clunky, but then I worked in I.T for sixteen years...". 4.5. Self-directed, 79% (15)The process of taking responsibility for one's own behaviour and well-being, appears to instil clients with a sense of independence and control.

P3, medium-range WAI-SF-C score:

"Other times it was good kind of to do a time and also independence, kind of learning to do stuff without a therapist there...I quite liked that I could, I don't know for me because it, I suppose it ties back into the independence thing, but because I was doing it on my own I almost proved I could do it on my own...because I feel like sometimes with a therapist you almost become like dependent on them or, it's like being taught something, when you're like dependent on the teacher."

WAI-SF-C: Working Alliance Inventory Short Form – Client.

DISCUSSION

463 Statement of principal findings

The results of the study present a preliminary conceptual framework of WA in b-CBT. It can be seen that Bordin's [9,10] 'bond', 'goals' and 'task' appear to be relevant in blended formats of CBT, however the priorities of WA demands have shifted to meet the client needs within a blended format. Moreover, an entirely new category 'usability heuristics', emerged as a novel means of promoting a new level of WA through a process of self-directed discovery and autonomous problem solving. Participants also explained that different modes of delivery by the PWP (e.g. client-provider bond, responsive support) and the digital program (e.g., upholding goals, task and promoting usability heuristics) were useful for meeting different WA demands.

473 Strengths and limitations of the study

474 To our knowledge, this study appears to be the first to provide an account of WA in b-CBT,475 and insights on how different treatment roles within a blended format of therapy, are used to

Page 29 of 51

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meet different WA demands. This is especially important given that, digital technologies are increasingly being used to treat mental health conditions, [4] and that WA plays an important role in promoting positive therapeutic change.[12] The design of our study had two key strengths. First, we used the most comprehensive and commonly used theory of the 'alliance' to approach our study.[36] Second, involving patient involvement enabled the project to be grounded on the needs and interests of people who have experienced mental health conditions and service use, thereby enhancing the application of the findings.[23] There are also several limitations to be noted. Our study does not include the PWP's perspective, which may have provided additional insights on WA in b-CBT, [18] however, this will be explored in a separate paper. Our sample was limited to 19 individuals with a primary diagnosis of mild-to-moderate depression who mostly reported moderate to high WA, were largely male, British white or white other and university educated, thereby limiting the representativeness of people seeking treatment in the UK[37] and restricting the generalisability of our findings. Exposure to only one type of digital program, may have influenced participant's experience of WA. For instance, a computerised platform that doesn't work adequately might generate more data on the importance of 'ease of use', than one that does. Some of these issues were pre-empted ahead of the study. Efforts were made to strengthen the conceptual framework in two ways. First, emerging participant data was guided by key literature on the alliance and patient involvement input. Second, our qualitative data analysis avoided the use of surface level themes, such as specific technological design. Instead, latent thematic analysis was used to unearth underlying psychological processes.[33]

498 Strengths and weaknesses in relation to other studies, discussing important differences in
499 results

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Participants fed back that, while it was essential for therapeutic activities to be complimentary between modes of delivery, they also suggested that modes of delivery can uniquely meet different WA needs. For instance, participants unanimously fed back that the PWP played an essential role in establishing the 'bond'. The role of the practitioner in supporting digital interventions is well documented in the literature.[6] A recent study evaluating the relationship between the client, the human provider and their c-CBT program, found that participants rated their overall treatment approach higher when they experienced c-CBT that was guided by a human provider compared to c-CBT that was unguided.[7] Another study evaluating the expectations of clients and practitioners in c-CBT for depression found that personalised interactions with a therapist were key[38] When attempts were made to unpack the importance of the therapist's role, participants suggested that the PWP's physical presence facilitated the PWP's propensity to convey important features of the bond (sub-themes 1.1-1.3) through verbal and non-verbal communication. This aligns with early psychotherapy research by Karl Rogers[39], who proposed that a therapists ability to display active listening (empathic understanding, unconditional positive regard, and congruent behaviour) was important for positively changing the impressions of the client's perceived negative experiences. Neuroscientific research evaluating the impact of active listening, suggested that the participant's recognition of active listening behaviour in another, can positively change the appraisal of an emotional episode and increased positive impressions of the active-listener.[40] These findings appear to be unique to human-to-human interactions. One study assessing the therapeutic alliance in a digital mental health mobile application for psychosis found that the anthropomorphizing of digital devices was not accepted by clients or mental health practitioners.[20] Given that little gains have been made to effectively deploy emotional artificial intelligence, a tool that is required for the effective biomimicry of human-beings in

Page 31 of 51

BMJ Open

the digital space,[41] the exclusion or non-effective deployment of a human provider in digitalpsychological interventions may therefore compromise the quality of WA.

On the other hand, participants reported that while the PWP was essential for the effective delivery of psychotherapy, participant's preferred blended delivery compared to PWP delivery alone. Almost all participants reported WA benefits, in the form of engagement, to digital delivery (i.e. 'usability heuristics'), through desired opportunities to engage in self-directed therapy. Our findings are echoed in the digital mental health user-experience and the alliance literature, which indicate that digital psychotherapy can enhance the client's perceived control, autonomy and feelings of empowerment, when sufficient human support is provided.[20,42] Our findings suggest that digital delivery within a b-CBT format cannot be disentangled from WA. For instance, a digital program that was perceived as non-interactive appeared to cause ruptures in engagement with 'activity-based task'. Given that digital delivery appears to have a significant impact on engagement with 'activity-based task', we argue that the inclusion of features that uphold existing alliance structures should therefore be accounted for in the WA framework. Our findings align with Bordin's [9,10] conceptualisation of WA, in which he proposed that the therapeutic tool cannot be disentangled from the means in which the alliance is built. This therefore suggests that the client-program WA can have an impact on the client-PWP WA, and vice-versa, contrary to research findings that suggest that WA contributions are independent and additive.[7]

The 'task' appears to play a central role in b-CBT, as initially theorised by Bordin[9,10]. Our findings appear to address Bordin's[10] call to distinguish between the task that is in service of 'building WA' (responsive support) and the tasks in the service of 'change' (activity basedtask). While many of the 'task' sub-themes appear to be novel to Bordin's[9,10] WA, with the exception of complementary tasks (sub-theme 3.3), all other 'task' sub-themes, are in fact implicit in his broad conceptualisation. The integration of technology in psychotherapy has Enseignement Superieur (ABES) . Protected by copyright, including for uses related to text and data mining, AI training, and similar technologies.

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prompted a re-evaluation of the demands placed on WA by a blended psychotherapeutic format. For example, the concept of accountability is implicit and forms one of many appendages associated with the PWP's role in building and maintaining WA. However, this concept has been propelled to the forefront as an essential ingredient for maintaining the alliance in b-CBT, in line with David Mohr and colleagues' 'supportive accountability' model for e-health.[43]

While 'bond', 'task' and 'usability heuristic' emerged as distinct themes, the 'goals' appears to be especially interlinked to the 'task'. The data from the qualitative interviews indicated that 'goals' was grounded in 'goals-setting activities'. This however diverges from Bordin's[9,10] description of the goals, which appears to move further, to address the PWP's efforts to unearth the core struggles that have bought the client to psychotherapy, in great detail[10]. One possible reason for our findings may be explained by the time-lag between the assessment and the first therapy session, which may have led participants to only focus on their course of b-CBT and not the proceeding assessment where more in-depth explorations of the client's struggles and goals may have taken place. On the other hand, our study is not the first to question the operational distinctiveness of the 'goals' and the 'task'. The psychometric evaluation of the Working Alliance Inventory (based on Bordin's [9,10]WA) suggested that these concepts were highly interrelated, [30] while a more recent psychometric evaluation found that goals and task did not emerge as distinct factors.[44]

569 Meaning of the study: possible explanations and implications for clinicians and 2 570 policymakers

571 Our findings address, at least in part, three of the 10 clinical and research priorities of digital 575 572 technology in mental health care identified by people with lived experience of mental health 587 573 conditions, carers and health and social care practitioners (See Box 1).[8] WA, a common 579 60 Page 33 of 51

BMJ Open

element of psychotherapy appears to be both relevant and important in b-CBT for depression. Human delivery appears to be central to the maintenance of empathy, gestures and non-verbal cues in which the PWP's role in b-CBT may focus on establishing the bond, and developing and maintaining the client's engagement through responsive support (Q8). Participants noted that both modes of delivery collaboratively contributed to the building of the alliance through distinctive pathways. While human support is perceived as 'responsive' and 'meaningful', digital delivery appears to promote autonomy and self-directed discovery (e.g. accessibility and self-directed therapy) and plays an important role in maintaining WA across 'goal' and 'task' activities (e.g. ease of use, interactivity of digital program and aesthetic appeal). Our findings appear to indicate that removing human support, seen as essential for the 'bond' and 'responsive support', may increase the risk of therapeutic ruptures and disengagement with psychological interventions delivered using a blended format (Q1 and Q3). These findings can be used to promote WA in technological design and clinical practice, thereby promoting engagement to b-CBT interventions for depression, and the effective deployment of PWP and digital support resources.

Box 1. Top ten research priorities for digital technology in mental health care, identified by the Priority Setting Partnerships [7].

Q1. What are the benefits and risks of delivering mental health care through technology instead of face-to-face and what impact does the removal of face-to-face human interaction have?

Q3. How can treatment outcomes be maximised by combining existing treatment options (medication, psychological therapies, etc.) with digital mental health interventions

Q8. Can the common elements of therapy (eg, empathy, gestures, non-verbal cues) that come from personto-person interactions be maintained with digital technology interventions?

590 Unanswered questions and future research

57 591 We propose four directions for future research. First, while our findings outline WA demands
59 592 in b-CBT, it is unknown if fulfilling such demands will lead to positive clinical change. Future

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> research should aim to investigate if self-reported WA as defined by our conceptual framework, predicts therapy outcome. Second, WA should be further explored across different computerised programs, clinical groups, higher-intensity interventions and other digital technologies (e.g. virtual experiences, gamification and text-based interventions) intended for use within a blended format, especially in relation to understanding the demands of different digital technologies in shaping 'usability heuristics'. Third, our findings can be used to inform the design of behavioural intervention technology theories, as a means of enhancing engagement and adherence to the digital components of blended interventions for mental health conditions. Fourth, given the promising potential of harnessing digital technologies for bridging the gap in mental healthcare in low resource settings[45], future research should examine WA in digital mental health interventions in non-western cultures and settings.

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Page 35 of 51

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Fig 1. Participant reported working alliance demands in a blended cognitive behaviouraltherapy intervention.

777 FOOTNOTES

778 Contributorship statement

Asmae Doukani (AD) developed the concept of the work. Patient involvement shaped the focus of the research. AD led all aspects of patient involvement. The design and analysis of the patient involvement focus groups was contributed to by Sarah Smith (SS), Jesus Montero-Marin (JMM), Caroline free (CF) and Ricardo Araya (RA). Arlinda-Cerga Pashoja (ACP) assisted with the patient involvement focus groups. AD, CF, SS significantly contributed to the design of the qualitative participant interview. AD led all aspects of data collection, analysis and interpretation. CF and Daniel Michaelson (DM) analysed a portion of the data independently. The iterative development of the conceptual framework was led by AD, overseen by DM and Ritsuko Kakuma (RK), and contributed to by CF, RA, and ACP. AD prepared all iterations of the manuscript, with significant contributions from RK, CF, DM, RA, JMM, SS and ACP.

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European Commission's Seventh Framework Programme (Health), grant agreement number
603098.

Conflict of interest: All authors have completed the ICMJE uniform disclosure form at 801 www.icmje.org/coi_disclosure.pdf and declare: no support from any organisation for the 802 submitted work; no financial relationships with any organisations that might have an interest 803 in the submitted work in the previous three years; no other relationships or activities that could 804 appear to have influenced the submitted work.

Ethical approval: The project was approved by the Health Research Authority's Ethics
Committee on 17th April 2015 (REC reference: 15/LO/0511) and the London School of
Hygiene and Tropical Medicine Research Ethics Committee on 9th June 2015 (Ethics Ref:
9409).

809 Transparency declaration: The lead author (AD) affirms that this manuscript is an honest,
810 accurate, and transparent account of the study being reported; that no important aspects of the
811 study have been omitted; and that any discrepancies from the study as planned (and, if relevant,
812 registered) have been explained.

B13 Data sharing statement: The datasets generated and analysed during the current study are
available from the corresponding author on reasonable request

^{iv} A participant who was allocated to the treatment as usual group was erroneously put forward as a suitable b-CBT candidate. This case was discovered during the interview, and corroborated with the E-compared trial manager after the interview. Data for this participant was not analysed.

ⁱ The use of the 'alliance' as a singular, broadly refers to the client-therapist alliance, and not to a specific variation (e.g. therapeutic alliance, working alliance, helping alliance etc.,) which while at times used interchangeably, have distinct theoretical underpinnings.

ⁱⁱ PPI was enlisted before the focus of the project was finalised, therefore people with a range of lived experiences were invited to be involved.

ⁱⁱⁱ The PWP workforce provide short-term, evidenced-based treatment in line with National Institute for Health and Care Excellence (NICE) guidance, to help people manage symptoms of mild to moderate depression and/or anxiety.

^v The aim of the study was to explore the relevance of the working alliance and to adapt the theory for the context of a b-CBT intervention. During the data analysis phase, it was decided that emerging data that fitted with Bordin's[9,10] conceptualisation, would be labelled according to existing categories (bond, goal, task). However, while the labels broadly fit with Bordin's[9,10] key categories, these labels are specific to b-CBT WA demands.

^{vi} WAI-SF-C scores are unavailable for participants who did not complete their online 3 month follow-up assessments on the E-Compared trial.

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Page 46 of 51

BMJ Open

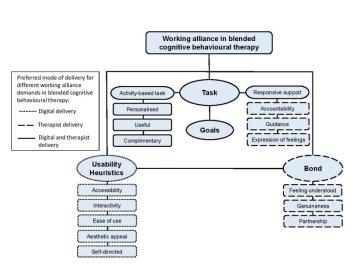


Fig 1. Participant reported working alliance demands in a blended cognitive behavioural therapy intervention.

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COREQ (COnsolidated criteria for REporting Qualitative research) Checklist

A checklist of items that should be included in reports of qualitative research. You must report the page number in your manuscript

where you consider each of the items listed in this checklist. If you have not included this information, either revise your manuscript

accordingly before submitting or note N/A.

Торіс	Item No.	Guide Questions/Description	Reported Page N
Domain 1: Research team			
and reflexivity			
Personal characteristics			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	
Occupation	3	What was their occupation at the time of the study?	
Gender	4	Was the researcher male or female?	
Experience and training	5	What experience or training did the researcher have?	
Relationship with			
participants			
Relationship established	6	Was a relationship established prior to study commencement?	
Participant knowledge of	7	What did the participants know about the researcher? e.g. personal	
the interviewer		goals, reasons for doing the research	
Interviewer characteristics	8	What characteristics were reported about the inter viewer/facilitator?	
		e.g. Bias, assumptions, reasons and interests in the research topic	
Domain 2: Study design			
Theoretical framework			
Methodological orientation	9	What methodological orientation was stated to underpin the study? e.g.	
and Theory		grounded theory, discourse analysis, ethnography, phenomenology,	
		content analysis	
Participant selection			
Sampling	10	How were participants selected? e.g. purposive, convenience,	
		consecutive, snowball	
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail,	
		email	
Sample size	12	How many participants were in the study?	
Non-participation	13	How many people refused to participate or dropped out? Reasons?	
Setting			
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	
Presence of non-	15	Was anyone else present besides the participants and researchers?	1
participants			
Description of sample	16	What are the important characteristics of the sample? e.g. demographic	
		data, date	
Data collection			
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot	
		tested?	
Repeat interviews	18	Were repeat inter views carried out? If yes, how many?	
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	
Field notes	20	Were field notes made during and/or after the inter view or focus group?	1
Duration	21	What was the duration of the inter views or focus group?	1
Data saturation	22	Was data saturation discussed?	
Transcripts returned	23	Were transcripts returned to participants for comment and/or	

Торіс	Item No.	Guide Questions/Description	Reported on Page No.
		correction?	rage No.
Domain 3: analysis and			
findings			
Data analysis			
Number of data coders	24	How many data coders coded the data?	
Description of the coding	25	Did authors provide a description of the coding tree?	
tree			
Derivation of themes	26	Were themes identified in advance or derived from the data?	
Software	27	What software, if applicable, was used to manage the data?	
Participant checking	28	Did participants provide feedback on the findings?	
Reporting			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings?	
		Was each quotation identified? e.g. participant number	
Data and findings consistent	30	Was there consistency between the data presented and the findings?	
Clarity of major themes	31	Were major themes clearly presented in the findings?	
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	

Once you have completed this checklist, please save a copy and upload it as part of your submission. DO NOT include this checklist as part of the main manuscript document. It must be uploaded as a separate file.

Reporting checklist for qualitative study.

Based on the SRQR guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SRQRreporting guidelines, and cite them as:

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		Reporting Item	Pag Numbe
Title			
	<u>#1</u>	Concise description of the nature and topic of the study identifying the study as qualitative or indicating the approach (e.g. ethnography, grounded theory) or data collection methods (e.g. interview, focus group) is recommended	
Abstract			
	<u>#2</u>	Summary of the key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results and conclusions	3
Introduction			
Problem formulation	<u>#3</u>	Description and signifcance of the problem / phenomenon studied: review of relevant theory and empirical work; problem statement	6
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BMJ Open	

		BMJ Open	Page 50
Purpose or research question	<u>#4</u>	Purpose of the study and specific objectives or questions	6-7
Methods			
Qualitative approach and research paradigm	<u>#5</u>	Qualitative approach (e.g. ethnography, grounded theory, case study, phenomenolgy, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g. postpositivist, constructivist / interpretivist) is also recommended; rationale. The rationale should briefly discuss the justification for choosing that theory, approach, method or technique rather than other options available; the assumptions and limitations implicit in those choices and how those choices influence study conclusions and transferability. As appropriate the rationale for several items might be discussed together.	8-15 Protected by copyright, including for uses related to text and dat 12
Researcher characteristics and reflexivity	<u>#6</u>	Researchers' characteristics that may influence the research, including personal attributes, qualifications / experience, relationship with participants, assumptions and / or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results and / or transferability	a 1
Context	<u>#7</u>	Setting / site and salient contextual factors; rationale	12-13 n
Sampling strategy	<u>#8</u>	How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g. sampling saturation); rationale	3, and similar techn 8
Ethical issues pertaining to human subjects	<u>#9</u>	Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues	12-13 12-13 9 9 12-13
Data collection methods	<u>#10</u>	Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative	12-13

Page 51 of 51			BMJ Open	Π
1 2 3 4			process, triangulation of sources / methods, and modification of procedures in response to evolving study findings; rationale	BMJ Open: first published 8-7, 12- 13
5 6 7 8 9 10 11	Data collection instruments and technologies	<u>#11</u>	Description of instruments (e.g. interview guides, questionnaires) and devices (e.g. audio recorders) used for data collection; if / how the instruments(s) changed over the course of the study	Published as 10.11;
12 13 14 15 16	Units of study	<u>#12</u>	Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	36/bmjopen-201 tected by copyr 15
17 18 19 20 21 22 23 24	Data processing	<u>#13</u>	Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymisation / deidentification of excerpts	as 10.1136/bmjopen-2019-036299 on 23 Septem Ensi 15 15 13-15 13-15
25 26 27 28 29 30 31	Data analysis	<u>#14</u>	Process by which inferences, themes, etc. were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale	tember 2020. Downloa Enseignement Superie ses related to text and 12-15
32 33 34 35 36 37	Techniques to enhance trustworthiness	<u>#15</u>	Techniques to enhance trustworthiness and credibility of data analysis (e.g. member checking, audit trail, triangulation); rationale	9-12, ded from http:/ ur (ABES) . 14-15 14-15
37 38 39	Results/findings			/bmjop I trainii
40 41 42 43 44	Syntheses and interpretation	<u>#16</u>	Main findings (e.g. interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	en.bmj.com/ o ng, and similar 15-25
45 46 47 48	Links to empirical data	<u>#17</u>	Evidence (e.g. quotes, field notes, text excerpts, photographs) to substantiate analytic findings	15-25 15-25 15-25
49 50	Discussion)25 at , es.
51 52 53 54 55 56 57 58	Intergration with prior work, implications, transferability and contribution(s) to the field	<u>#18</u>	Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application /	14-15 similar technologies. 15-25 at Agence Bibliographique de 15-25 15-25 at Agence Bibliographique de 15-25 25 26-31
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	Limitations	<u>#19</u>	Trustworthiness and limitations of findings	26-31	irst pul
	Other				blished
	Conflicts of interest	<u>#20</u>	Potential sources of influence of perceived influence on study conduct and conclusions; how these were managed	38 Protecte	d as 10.1136/br
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