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Pilot randomised controlled trial of Help4Mood, an embodied virtual agent-based system to support treatment of depression

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ABSTRACT

Introduction

Help4Mood is an interactive system with an embodied virtual agent (avatar) to assist in self-monitoring of patients receiving treatment for depression. Help4Mood supports self-report and biometric monitoring and includes elements of cognitive behavioural therapy.

We aimed to evaluate system use and acceptability; explore likely recruitment and retention rates in a clinical trial and obtain an estimate of potential treatment response with a view to conducting a future randomised controlled trial (RCT)

Methods

We conducted a pilot RCT of Help4Mood in three centres, in Romania, UK and Spain. Patients with diagnosed depression (Major Depressive Disorder) and current mild/moderate depressive symptoms were randomised to use the system for 4 weeks in addition to treatment as usual (TAU) or to TAU alone.

Results

Twenty-seven individuals were randomised and follow up data were obtained from 21 participants (12/13 Help4Mood, 9/14 TAU). Half of participants randomised to Help4Mood used it regularly (more than 10 times); none used it every day. Acceptability varied between users. Some valued the emotional responsiveness of the system, while others found it too repetitive. Intention to treat analysis showed a small difference in change of BDI-2 scores (Help4Mood -5.7 points, TAU -4.2). Post-hoc on-treatment analysis suggested that participants who used Help4Mood regularly experienced a median change in BDI-2 of -8 points.

Conclusion: Help4Mood is acceptable to some patients receiving treatment for depression although none used it as regularly as intended. Changes in depression symptoms in individuals who used the system regularly reached potentially meaningful levels.

(245 words)

INTRODUCTION

Depression is the most common mental disorder worldwide[1] and affects at least 5% of the population in Europe.[2] Its impact on quality of life and morbidity are similar to those of other chronic conditions such as rheumatoid arthritis and diabetes.[3] Most people with mild or moderate forms of clinical depression (Major Depressive Disorder) are treated in the community with pharmacological or psychological therapies, often in primary care. They usually receive relatively infrequent contact with their treating clinician.

Computer- or Internet- delivered Cognitive Behaviour Therapy (CCBT/ICBT) can increase patients' access to psychological treatments for depression but requires additional clinician support (which can be provided face to face or via the telephone) in order to lower attrition rates[4] and increase effectiveness[5]. Standard ICBT packages rely primarily on self-report and do not accommodate objective measures such as activity[6] or speaking patterns[7] that have been shown to correlate with depressive symptoms.

Help4Mood is a novel computer application designed to support people undergoing treatment for depression between appointments with their clinician. It uses self-monitoring of mood, thoughts, activity and speech to generate new information for both patient and clinician and encourages patients to reflect on common patterns of negative thinking using elements of CBT. Help4Mood was developed in an iterative process, including people with depression and clinicians treating depression[8,9] It is designed to be used by patients who have been diagnosed with depression, have

current depressive symptoms, are well enough to undertake regular self-monitoring, and are unlikely to require urgent crisis support.

In Help4Mood, standard symptom self-report tools that include mood, sleep, thoughts, and behaviours are supplemented by accelerometer measurement of physical activity and acoustic analysis of speech. Patients interact with Help4Mood using a simple Graphical User Interface that features a Virtual Agent which talks users through exercises and activities and varies content of responses and facial expressions in response to user input. The main aim of the Virtual Agent was to promote user engagement and adherence. The user interface is shown in Figure 1.

FIGURE 1 ABOUT HERE

Help4Mood includes simple elements of cognitive behavioural treatments to guide self-reflection and provides regular summaries of progress for the patient and their supervising clinician, which are designed to provide a succinct overview of any changes in the patient's conditions and can be discussed during consultations.

We aimed to conduct a pilot randomised controlled trial of Help4Mood in order to (a) evaluate system use and acceptability in patients with depression; (b) examine likely recruitment and retention to a substantive clinical trial of Help4Mood; (c) obtain an estimate of potential treatment response for use in planning a formal efficacy trial.

METHODS

We conducted a pilot randomised controlled trial with two parallel groups, Help4Mood (H4M) plus treatment as usual (TAU), and TAU only. The trial ran in three sites, one each in the UK, Romania, and Spain.

Patients with major depression diagnosed by their treating clinician and who had current depressive symptoms were recruited to a trial in which they were allocated to one of the two groups. Full details of the trial sites and trial procedures for patient identification and enrolment are described in Supplementary File 1 .

Relevant ethical approvals were obtained for each site. The study was registered with a clinical trials database (ISRCTN 87615455).

Participant identification and enrolment

Patients were invited in writing by clinicians in the three countries from their active caseloads and by identification through practice computer searches. As this study involved patients currently receiving treatment from their clinician we used the treating clinician's diagnosis backed up by self-report measures of depressive symptoms rather than a formal psychiatric interview schedule.

 Interested individuals were then seen in person to assess eligibility, and complete informed consent, if eligible. Following consent, participants completed baseline questionnaires, underwent randomisation and arranged an appointment to receive the Help4Mood intervention.

Eligibility and exclusion criteria

Participants were eligible if they met all of the following criteria: age 18-64, clinical diagnosis of major depressive disorder; if taking anti-depressant medication, no change in the last four weeks.

Participants were excluded if they met any of the following criteria: baseline Beck Depression Inventory II[15] (BDI-2) below 10 or greater than 30; significant thoughts of self-harm or suicide; history of recent self-harm, substance abuse, bipolar disorder, psychosis or learning difficulty; currently receiving specialist psychological therapy; on augmented antidepressant therapy;

Randomisation and treatment allocation

Randomisation was conducted by an independent statistician using a variable block design. Allocations were sent to independent coordinators at each site and then prepared in sealed opaque envelopes to be opened after completion of the informed consent process and baseline measures. Outcome measures were collected un-blinded to participant allocation but primary data analysis was conducted blind to allocation.

Intervention package

Help4Mood consists of three main components, a Personal Monitoring System (PMS), a Decision Support System (DSS), and a Virtual Agent Interface.[10]

Monitoring within Help4Mood is conducted by completion of on-screen items, guided by the talking virtual agent. The PMS focuses on activity monitoring with an accelerometer, which users choose to either wear on the wrist or carry in a pocket.[11] The DSS plans user sessions to provide variety and ensure sufficient data on self-reported symptoms is collected across a week[12]. The DSS generates short, medium and long sessions and the user selects their preferred session length each time they use

the system. A full list of components can be found in Table 1. The only component patients saw every day was the Daily Mood Check, which was based on the CES-D-VAS-VA.[13]

TABLE 1 ABOUT HERE

The Virtual Agent is an animated human-based character whose gender, clothing style (formal/informal), voice, and language (English, Spanish or Romanian) are selectable during configuration for an individual. The Agent adapts speech content, delivery and facial expression in response to the user's actions; reactions are determined using a flexible cognitive emotional model.[14]

Help4Mood contains two safety components. First, there is a "crisis plan" with personalised contact numbers and distress management behaviours, which is available at any time through the user interface. Secondly, the patient's overall depressive symptoms are assessed every week using the PHQ9[23]. Should the PHQ9 deteriorate by two points or more compared to the previous score, or should the patient indicate more than occasional thoughts of self-harm, Help4Mood prompts the participant to consider contacting "a professional or other person", followed by the crisis plan. From that point on, only basic mood check data is collected; other system functions are unavailable.

Help4Mood was provided on a standard laptop computer rather than online because of the processing demands of the DSS and the Virtual Agent. Access was via a password-protected account, and the computer software was limited to the minimum applications necessary to support the Help4Mood system. The computer was supplied with internet access to transmit encrypted progress reports from Help4Mood, but was

otherwise locked down, to ensure optimal protection of the confidential patient data generated.

Use of Help4Mood

Participants randomized to Help4Mood were requested to use the system every day in their own home. Because of the content of the system, they were advised to use it in personal time or a private space. They were also asked to schedule appointments with their usual clinician, either face to face or by phone, at two weeks and at four weeks to discuss any reports generated by the Help4Mood system.

Treatment as Usual

TAU was provided to both allocation groups and comprised regular (fortnightly) scheduled appointments, additional appointments if needed and continuation of existing treatment as per the relevant local health systems and practices.

Follow up

Participants randomised to Help4Mood were contacted by the researcher after 2 weeks by telephone to check for any problems. All participants were invited to a follow up assessment four weeks after randomisation or beginning to use Help4Mood. Non-attenders received one further follow up telephone reminder.

Outcomes

Assessment of system use and acceptability

The Help4Mood system recorded detailed logs of system use and these were retrieved at the end of each four week period of use. The number and duration of times that each component of Help4Mood was used, and all monitoring data were extracted. Participants allocated to Help4Mood were debriefed in a semi-structured interview

which explored their experience of using the system and their views on the individual components. Interviews were transcribed and analysed using thematic analysis.

Measures relating to depression

At baseline and four weeks participants completed the Beck Depression Inventory II (BDI-2)[15]; the Quick Inventory of Depressive Symptoms - Self-Report (QIDS-SR)[16]; Dysfunctional Attitude Scale - Short Form 2[17] (DAS-SF 2, a measure of common negative cognitions) and the EQ-5D-5L generic quality of life measure.[18]

Sample Size and Statistical Analysis

We aimed to recruit 52 participants, but owing to time constraints and lower than expected uptake by potential participants the study was closed after 28 participants were recruited.

Analysis

Questionnaire data were summarised using mean and standard deviation and plotted to examine individual changes. While this study was not powered to show statistically significant differences between allocation groups, we examined changes from baseline in BDI-2, QIDS-SR, EQ-5D-5L and DAS-SF2 in each group. Where data at follow up were missing we did not attempt to impute data. There were no pre-specified subgroup analyses, however we conducted a post hoc comparison of changes in BDI-2 between participants randomised to Help4Mood who were high and low users, based on the number of sessions and total time spent using Help4Mood.

RESULTS

Participant identification, recruitment and retention

In total 52 patients expressed an interest in taking part and following eligibility screening and explanation of the study 28 patients were randomised, 14 to Help4Mood and 14 to TAU. The CONSORT diagram for this study is shown in Figure 2. Owing to an administrative error one Spanish patient randomised to TAU was incorrectly given the Help4Mood system. The patient was allowed to continue using the system but their data were excluded from the analysis.

FIGURE 2 ABOUT HERE

Eleven of the 13 (85%) participants correctly allocated to Help4Mood completed follow up measures between 4 and 6 weeks after randomization. One was withdrawn, and completed follow up measures early, because a routine PHQ measure within Help4Mood returned a score which met the critical threshold of 2 or more points above baseline discussed above. Although this triggered an alert and study withdrawal, the participant had not perceived any worsening of mood.   Five (33%) participants allocated to TAU did not respond to invitations to complete follow up measures.

Participant Characteristics

Participant characteristics are shown in Table 2. Help4Mood and TAU groups were comparable with regard to sex, education, age, and medication status.

TABLE 2 ABOUT HERE

Table 2 also contains baseline scores of depressive symptoms and other measures. The mean BDI-II score was 20.7 (SD 7.7). Based on the BDI-II score, depressive symptoms were mild (less than 20) in 14 (52%), moderate (20-28) in 6 (22%) and severe (29 or 30) in 7 (26%).

Acceptability of Intervention

Data on the use of Help4Mood were available from 12 participants: equipment failure resulted in data loss from one participant. The median number of times that Help4Mood was used was 10.5 (twice a week or more) and the median total duration was 134 minutes. Two participants appeared to have used the system for only one or two days, three used it on 3—7 days (*casual users*), and six used Help4Mood at least twice a week (10 times or more, *regular users*). Details of the number and length of session are reported in supplementary file 1.

Estimates of Potential Treatment Effects

Table 3 shows the post treatment values, and differences from mean baseline values for the measures of depressive symptoms and cognitions and quality of life. The large change seen in EQ-5D-5L was accounted for by a marked spontaneous improvement in one participant allocated to TAU.

TABLE 3 ABOUT HERE

The BDI-2 scores of both groups improved. Since usage data for the Help4Mood system showed a clear distinction between regular and casual users, we also calculated the change in BDI-2 for each user group. Regular users showed a median reduction of 8 points as opposed to 3 points for casual users. A reduction in BDI-2 from baseline of 5 or more points or 30% is regarded as representing a clinically important difference[19].

Participant Feedback

Since a detailed qualitative analysis of participant feedback is outside the scope of this paper, we focus on key themes that concern the two most innovative components, the embodied Virtual Agent and the DSS. Both were designed to maintain user engagement and address the tedium of answering the same questions each day.

Almost all of our participants would use Help4Mood for themselves, once a final version had been developed, and would recommend it to other people with depression.

> *"I think it is a useful system. For me at least, it was very helpful in some moments when I felt low and I did those exercises. It gave me some energy. I hope you will improve it so that it can be more useful." (RO12, female, Romania)*

Participants were divided in their response to the Agent, whose behaviour had been modelled on that of a friendly, but professional therapist. Overall, they liked the ability to customise gender and appearance. Some valued the Agent's responsiveness and appeared to have established a relationship with it. For example, at the exit interview, participant RO10 said of her female Agent, "I will miss her." Others, however, found their Agents too cold and repetitive.

Participants also differed in the amount of realism they required of the Agent. While participant SCO01 criticized the Agent for not being sufficiently realistic, participant SCO06 requested less realism, and would have been happy with a cartoon animal.

Most participants noticed clear differences between sessions of different lengths, and appreciated the opportunity to tailor session length to their needs.

> *"I could choose the type of session I wanted… if one day I needed a long session, I could choose a long one. Sometimes, when I was not in a good mood I could choose a shorter version and I liked that." (RO14)*

Despite the variation provided by the DSS, participants grew tired of performing a similar set of tasks in every session. They requested a more customizable experience that allowed them direct access to the parts of Help4Mood they preferred and suggested additional content such as psychoeducation.

DISCUSSION

Help4Mood is the first computer-based system to support depression treatment that uses an onscreen embodied Virtual Agent to maintain user engagement. It was developed iteratively with potential users (patients and clinicians) and designed to complement existing care. While the overall results only indicate a small improvement in mean BDI-2 scores, regular users appeared to obtain a greater benefit than non-regular users and the effect seen in regular users was potentially meaningful. Acceptability, adherence and outcomes were broadly similar between the two larger sites in Scotland and Romania.

Strengths and limitations

Although a case study series involving an earlier prototype with almost full functionality suggested high acceptability of Help4Mood,[20] in this trial, almost all participants found it inconvenient or inappropriate to use Help4Mood every day as intended.

It appears that daily symptom tracking may be less attractive for this patient group than has been found for bipolar disorder, a condition characterised by susceptibility to both depressive and manic episodes.[21]

Another reason for irregular use was that Help4Mood required a dedicated laptop. A laptop was necessary because of the computational requirements of the stable research prototype used for the trial. Dedicated laptops were set up by the research team to ensure optimal data protection, which is particularly important for stigmatised conditions such as MDD, and seamless communication with the specially developed actigraphy devices. Before undertaking a substantive trial, an app version of Help4Mood for tablet computers should be developed that requires fewer computational resources while maintaining user privacy.

Future versions of Help4Mood should also allow greater flexibility in accessing components and planning sessions. The Virtual Agent, which is currently designed to behave like a professional therapist, needs to be extended with an additional, warmer, more expressive persona.

The recruitment rate was lower than we have found in our previous trials of ehealth interventions[21] but comparable to that for primary care trials of complex depression interventions in the UK.[22] The commonest reason for exclusion of potential participants prior to enrolment was a BDI-2 score outside the prescribed range. We did not identify any reason for low recruitment in Spain which should influence the results.

This illustrates the difficulty in undertaking pilot research in sensitive or higher-risk conditions, since clinicians may be reluctant to recommend an unproven addition to conventional treatment, and patients may be reluctant to try innovations that have not been strongly recommended by their clinicians.

Nevertheless, the increased uptake and availability of mobile and online mood trackers – only a minority of which are scientifically validated - suggests that a

system like Help4Mood can address an important patient need and should be investigated further. However, before embarking on a future trial, Help4Mood should be redesigned to include more components, permit more flexible sessions, and allow delivery via mobile devices.

CONCLUSIONS

Help4Mood, a novel virtual agent-based system to engage patients with depression in monitoring and treatment, was associated with potentially meaningful improvements in symptoms of depression among users who engaged regularly with it over the course of a four week trial. Virtual agent-supported treatments can potentially be a valuable part of caring for patients with depression, but further research is needed to establish the user groups most likely to benefit and the components most likely to be useful and effective.

Acknowledgements

Competing Interests

None declared

Guarantor and Statement of Contributorship
Guarantor: Christopher D Burton. CB, BMcK, AST, and MW designed the study. CB planned and performed statistical analysis with assistance from MW, and MW, BMK, MMN, and CB performed qualitative data analysis. BMcK, MMacN, CM, and CB implemented the trial in Scotland, AST, SM, RM, and DD implemented it in Romania, and ASB implemented it in Spain. EF provided technical support and advice during the entire study, and CM managed the Help4Mood project. CB drafted the paper, with assistance from BMcK, MW, and CP, and all authors contributed to the interpretation of the results and commented on the draft paper. Lucy McCloughan, Centre for Population Health Sciences, University of Edinburgh was an additional key contributor, who coordinated the implementation of the trial in Scotland.

Ethics approval

Ethical approval for T6.8 was obtained from the NHS South East Scotland Research Ethics Committee 1 on November 14, 2013 (reference number 13/SS/0207); the Ethics Committee of Babes-Bolyai University on December 12, 2013 (reference number CMCS: 34839), and from the Ethics Committee of the IDIAP Jordi Gol on March 3, 2014 (reference number P14/020).

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Table 1 Functionality of the Help4Mood GUI

Daily Mood Check	CES-VAS-VA[13]
Weekly Mood Check	PHQ-9 [242]
Negative Thoughts Module	patients identify negative cognitions about a recent event and are challenged to consider a more positive interpretation. Items were taken from checklists of dysfunctional cognitions associated with depression,[17, 25, 26]
Positive Thoughts Module	patients identify positive cognitions about a recent event, based on positive reframing of items in the Negative Thoughts Module
Sleep Questionnaire	covers sleep duration, latency and disturbance
Speech Measurements	three tasks including semiautomatic speech and a category fluency task
Behavioural Activation	based on tasks from lists of activities commonly used in behavioural activation.
Relaxation Exercises	relaxation, grounding and visualisation techniques based on conventional psychological treatment, recorded for Help4Mood in each language.

Table 2 Participant characteristics and baseline measures

		Treatment as Usual	Help4Mood
Sex			
	Female	8	10
	Male	6	3
Education			
	School	9	4
	Higher	5	9
Site			
	Romania	9	9
	Scotland	4	3
	Spain	1	1
Current medication			
	No	6	8
	Yes	8	5
Age			
	Mean (SD)	42 (10.4)	35.3 (12.1)
Baseline measures			
BDI-2		21.8 (6.8)	19.6 (8.1)
QIDS-SR16		17.7 (6.2)	16.9 (7.2)
DAS_SF2		24.5 (4.2)	20.1 (5.4)
EQ-5D utility[1]		0.76 (0.19)	0.72 (0.21)
EQ-5D - VAS		62.6 (17)	73.2 (19.2)

BDI: Beck Depression Inventory, QIDS-SR: Quick Inventory of Depressive Symptoms- Self Report; DAS-SF: Dysfunctional Attitudes Scale Short Form; EQ-5D: EuroQol 5D 5Level; VAS Visual Analog Scale

[1] Utilities calculated using appropriate national tariffs.

Table 3, Mean changes from baseline of measures of depressive symptoms and cognitions and health related quality of life

	Usual Care			Help4Mood			Difference
	Mean	SD	change[1]	Mean	SD	change[1]	
BDI-2[2]	17.6	6.8	-4.2	13.9	8.1	-5.7	-1.5
QIDS-SR16[2]	14.7	6.2	-3	14.2	7.2	-2.7	0.3
DAS-SF2[2]	23.5	4.2	-1	18.1	5.4	-2	-1
EQ-5D Utility[3]	0.89	0.19	0.13	0.76	0.21	0.04	-0.09
EQ-5D VAS[3]	79.9	17	17.3	75.2	19.2	2	-15.3

BDI: Beck Depression Inventory, QIDS-SR: Quick Inventory of Depressive Symptoms- Self Report; DAS-SF: Dysfunctional Attitudes Scale Short Form; EQ-5D: EuroQol 5D 5Level; VAS Visual Analog Scale

[1]change from baseline values listed in Table 2

[2]For BDI, QIDS-SR and DAS-SF, lower values indicate better health

[3] For EQ-5D, higher values indicate better health

Supplementary File 1

Table showing number, type and duration of Help4Mood sessions by participant;

Patient[1] number	Individual sessions			Summary of sessions		
	Short	Medium	Long	Total sessions	Total time	Median duration
1	2	0	0	2	34	17
2	4	0	8	12	189	13
3	2	4	1	7	92	7
4	6	8	9	23	369	11
5	0	1	1	2	26	13
6	9	6	4	19	150	9
7	2	3	1	6	43	5
8	6	2	3	11	195	16
9	5	6	4	15	225	11
10	4	2	4	10	118	8
11	7	4	2	13	176	13
12	2	1	4	7	106	19
Total	49	37	41	127	1723	

[1] One participant not included because of technical failure resulting in loss of system log