Schizophrenia Research xxx (xxxx) xxx

Contents lists available at ScienceDirect

Schizophrenia Research

journal homepage: www.elsevier.com/locate/schres

Pilot randomised controlled trial of a brief coping-focused intervention for hearing voices blended with smartphone-based ecological momentary assessment and intervention (SAVVy): Feasibility, acceptability and preliminary clinical outcomes

Imogen H. Bell [a, *], Susan L. Rossell [a, b], John Farhall [c, d], Mark Hayward [e, f], Michelle H. Lim [a], Sarah F. Fielding-Smith [e, f], Neil Thomas [a]

[a] Centre for Mental Health, Swinburne University of Technology, Australia
[b] Department of Psychiatry, St. Vincent's Hospital, Australia
[c] Department of Psychology and Counselling, La Trobe University, Australia
[d] NorthWestern Mental Health, Melbourne Health, Australia
[e] Sussex Partnership NHS Foundation Trust, UK
[f] School of Psychology, University of Sussex, UK

ARTICLE INFO

Article history:
Received 12 January 2019
Received in revised form
25 June 2019
Accepted 10 October 2019
Available online xxx

Keywords:
Digital technology
Experience sampling methodology
Treatment
Psychosis
Auditory hallucinations
Blended therapy

ABSTRACT

Background: Voice-hearing experiences can be distressing and impairing, and existing psychological treatments show modest effectiveness. Ecological momentary assessment and intervention (EMA/I) are two promising approaches which may be used as digital tools to support and enhance existing psychological therapies. The aim of this study was to investigate the potential clinical utility of smartphone-based EMA/I in a blended, coping focused therapy for voice-hearing experiences. *Method*: This pilot RCT focused on feasibility, acceptability and preliminary estimations of efficacy. Thirty-four participants with persisting and distressing voices were randomised to receive the four-session intervention along-side treatment-as-usual (TAU) or TAU-only. *Results:* Findings supported the feasibility and acceptability of the approach, with good engagement and satisfaction rates, and clinical outcomes showed the intervention holds promise for improving coping, overall severity of voices and to some degree their negative impact. *Conclusion:* This is the first examination of the use of EMA/I in a blended therapy for psychotic experiences, with findings suggesting these technologies show promise as clinical tools.

1. Introduction

Psychological interventions, particularly cognitive behavioural therapy for psychosis (CBTp; Farhall and Thomas, 2013; Turkington et al., 2008), are recommended as a core component of treatment for hearing voices, or *auditory verbal hallucinations* (Galletly et al., 2016; NICE, 2010). However, effects sizes of CBTp are modest (Jauhar et al., 2014; van der Gaag et al., 2014), access is generally limited, and the treatment is costly and complex to deliver (Berry and Haddock, 2008; Schizophrenia Commission, 2012; Haddock et al., 2014; Ince et al., 2016).

Smartphones applications (*apps*) have unique capabilities that may provide novel and innovative ways to improve the effectiveness and reach of psychological treatments for psychosis (Bakker et al., 2016; Price et al., 2014; Proudfoot, 2013; Thomas et al., 2019; Treisman et al., 2016). Ownership of smartphones is wide spread in psychosis populations (Firth et al., 2015) and research has shown that these technologies can assist in illness self-management, reduce symptoms and their impact, minimise relapse, and promote physical health (Alvarez-Jimenez et al., 2014; Bell et al., 2017; Firth and Torous, 2015). Further, individuals with psychosis appear interested in using them regularly for their mental health (Bucci et al., 2018b; Gay et al., 2016; Torous et al., 2014).

Ecological momentary interventions (EMIs; Heron and Smyth, 2010) make use of smartphone technology to provide support in daily life by sending electronic prompts that encourage therapeutic behaviours in the moment they are needed. When used in

* Corresponding author. 35 Poplar Rd, Parkville VIC, 3052, Australia.
E-mail addresses: imogen.bell@orygen.org.au (I.H. Bell), neilthomas@swin.edu.au (N. Thomas).

https://doi.org/10.1016/j.schres.2019.10.026
0920-9964/

conjunction with standard therapy, EMI might promote generalisation of intervention strategies to daily life. This is a potentially important capability for the treatment of psychosis, where cognitive and motivational difficulties are common (Fioravanti et al., 2012; Johansen et al., 2011) and treatment engagement can be low (Dixon et al., 2016; Johansen et al., 2011). Studies have demonstrated the broad application of EMI in psychosis treatment, with support for feasibility, acceptability and promise for improving clinical outcomes (Bell et al., 2017).

Ecological momentary assessment (EMA; Shiffman et al., 2008) is a related approach which uses smartphone apps to deliver questionnaires in daily life at repeated intervals across several days. Greater reliability and ecological validity are afforded through measurement of phenomenon in the moment, in natural environments (Shiffman et al., 2008; Stone et al., 2007). Further, repeated measurement allows for the examination of temporal relationships between variables (Ebner-Priemer and Trull, 2009). Findings have supported the feasibility and reliability of using EMA in psychosis populations (Brenner and Ben-Zeev, 2014; Granholm et al., 2008; Palmier-Claus et al., 2012), however little research has investigated its use in clinical treatment (Bell et al., 2017; McDevitt-Murphy, Luciano and Zakarian, 2018).

EMA and EMI (EMA/I) may be useful within *blended therapies* for psychosis, involving the combined used of digital technologies with standard face-to-face therapies. In other clinical populations, studies have shown that these approaches may lead to more potent interventions (Erbe et al., 2017). It may be possible to adapt existing evidence-based treatments to incorporate technologies such as EMA/I to support therapeutic components. In the context of voice-hearing experiences, one such candidate therapy is *coping strategy enhancement* (CSE; Tarrier, 1992; Tarrier et al., 1990).

CSE is an idiographic, CBT-based psychological therapy aiming to improve coping with psychotic symptoms (Tarrier, 1992; Tarrier et al., 1990). Functional analysis is used to identify antecedents and responses to symptoms, which then informs the identification and subsequent implementation of individualised coping strategies. Trials have supported the clinical benefit of CSE approaches (Tarrier et al., 1993, 1998; Yusupoff and Tarrier, 1996), including in a brief format over four sessions targeting voices specifically (Hayward et al., 2018; Paulik et al., 2018).

Conceivably, such an approach may be enhanced by incorporating EMA to assist in initial functional analysis, providing data on variation in voices and related variables, and EMI prompts of individualised coping strategies may promote more consistent use of these in daily life. This highly novel application of EMA/I was the subject of this research, which aimed to examine the feasibility, acceptability and estimated clinical effects of a brief intervention which blended EMA/I with standard face-to-face therapy to improve coping with hearing voices [Smartphone-Assisted coping focused interVention for Voices (SAVVy)]. The development of the intervention and a case illustration is reported in Bell et al. (2018a).

2. Methods

Reporting followed CONSORT guidelines (supplementary) and ethical approval was provided by the Alfred Hospital Ethics Committee (project 440/16). The trial was prospectively registered (ACTRN12617000348358) and the study protocol was published before recruitment ended (Bell et al., 2018b).

2.1. Study design

A single-blind, parallel group, pilot RCT with a 1:1 allocation ratio to the SAVVy intervention plus treatment-as-usual (TAU) or TAU alone. TAU typically included standard care provided by a clinical team, including medication and case management. Trained researchers blind to treatment allocation completed assessments at pre-randomisation and approximately 8 weeks following randomisation. An independent researcher randomly allocated participants to groups used minimisation procedure using QMinim online software. Minimisation was used to balance continuous vs non-continuous voices across groups [Psychotic Symptom Rating Scales-Auditory Hallucinations (PSYRATS-AH; Haddock et al., 1999) item 1 score $\leq$3 versus 4], a variable which may be influenced by EMA/I.

2.2. Participants

Thirty-four adult participants were recruited through referrals to a specialist Voices Clinic and wider advertising to clinical services and consumer groups, between March 2017 and January 2018. The sample size was based on published guidelines (Julious, 2005; Sim and Lewis, 2012; Teare et al., 2014) and is consistent with similar recent pilot RCTs with this population (Bucci et al., 2018; Hazell et al., 2018). Eligibility criteria were: (1) over the age of 18 years; (2) proficient English language; (3) experiencing current, frequent (4 + times per week, or if less, lasting at least 1 h at a time) and distressing (score 1 + on amount of distress item of PSYRATS-AH (Haddock et al., 1999) voices for at least six months; (4) comfortable using a smartphone or willing to learn. Exclusion criteria were (1) unable to provide informed consent; (2) intellectual disability (estimated IQ < 70, measured by the Wechsler Test of Adult Reading (WTAR; Wechsler, 2001); (3) initiation of a new antipsychotic medication within the previous 8 weeks; (4) voices solely substance-related; (5) distress or agitation displayed during baseline assessment; and (6) requiring active crisis management.

2.3. Measures

Baseline measures included basic demographic and clinical information (e.g. medication dosages); use and familiarity with technology; Mini-International Neuropsychiatric Interview (Sheehan et al., 1998) for DSM-5 mental disorders; Structured Clinical Interview for DSM-5 (First et al., 2015) for borderline personality disorder diagnosis; Scale for the Assessment of Negative Symptoms (SANS; Andreasen, 1989); and Wechsler Test of Adult Reading (WTAR; Wechsler, 2001) to estimate intellectual ability.

Feasibility was the primary outcome measure, focusing on: completion rates of the EMA questionnaires (completers defined as having completed over 33% of the total number of EMA questionnaires), proportion of participants for whom EMA-based feedback summaries were produced; proportion of EMI reminders viewed; trial uptake and attrition; and fidelity to the intervention protocol (proportion of therapy checklist items endorsed by therapists as completed).

Acceptability was measured using a feedback questionnaire designed for the study. Participants completed the Credibility and Expectancy Questionnaire (CEQ; Devilly and Borkovec, 2000) after the informed consent procedure, of which the Credibility subscale was used to measure pre-conceived perceptions of the intervention credibility. Treatment group participants completed the Working Alliance Inventory – Short Revised (WAI-SR; Hatcher and Gillaspy, 2006) in relation to their rapport with the therapist.

The primary clinical outcome was PSYRATS-AH total score (Haddock et al., 1999). Secondary clinical outcomes included Depression, Anxiety and Stress Scale-21 total score (DASS-21; Lovibond and Lovibond, 1995) and the Subjective Experiences of Psychosis Scale –Negative Impact Subscale total score (SEPS; Gillian Haddock et al., 2011). Process measures included two visual analogue scales (VAS) to assess (1) confidence in coping with voices

Please cite this article as: Bell, I.H et al., Pilot randomised controlled trial of a brief coping-focused intervention for hearing voices blended with smartphone-based ecological momentary assessment and intervention (SAVVy): Feasibility, acceptability and preliminary clinical outcomes, Schizophrenia Research, https://doi.org/10.1016/j.schres.2019.10.026

day-to-day, and (2) awareness of patterns in voices, and two multiple choice items measuring the frequency of use of coping strategies and the number of strategies used.

2.4. Intervention

Details of the development and a case study illustrating the delivery of the intervention are reported elsewhere (Bell et al., 2018a). A depiction of the intervention procedure is displayed in Fig. 1. The intervention was split into two phases involving initial assessment and EMA monitoring for functional analysis, which informed the second phase involving identifying and implementing individualised coping strategies which were supported by personalised EMI reminders in daily life. An existing app called MovisensXS was used for the purpose of the trial. Participants were lent a smartphone if they did not already have a compatible Android phone (necessary to run the app).

Following the first session involving an introduction and training in how to use the smartphone app, participants completed six days of EMA monitoring involving the completion of a 39-item questionnaire (supplementary 2), ten times per day. EMA items measured common antecedents to voices (e.g. mood, anxiety), voice-related variables (i.e. intensity, distress, impact), and coping responses to the voices (e.g. listening to music, arguing with the voices). EMA items were determined based on an iterative approach involving reviews of the EMA literature on psychotic symptoms and coping with voices, feedback from lived experience consultants, researchers and clinicians in the field, and an initial pilot study (Bell et al., 2018a). This EMA period facilitated self-monitoring of voices, and provided data that was then statistically analysed using time-lagged multiple regressions to identify variables associated with fluctuations in voice intensity (see Bell et al., 2018a, 2018b). Summary statistics of questionnaires completion rates, voice intensity and distress, and coping strategies used were also computed. In line with recommendations in the literature, this feedback analysis was conducted if participants completed at least 33% of the total number of EMA surveys (Delespaul, 1995; Palmier-Claus et al., 2011). A simple, lay-person summary of this analysis was provided to participants in the second session, which was discussed in an exploratory manner to inform functional analysis of the voices. This functional analysis was used to identify alternative responses to the voices which may interrupt problematic maintenance cycles associated with their activity and improve overall coping. Individual coping strategies were worded as short sentences by the participant and programmed into the app. Participants then received five personalised EMI prompts per day for the following ten days after session two and were able to view their reminders on-demand. Eight evening EMA questions were used to monitor changes in the voices and helpfulness of the coping strategies, with feedback of this information then reviewed in session three and coping strategies could be updated if needed. This was followed by a further ten-day EMI period and evening EMA questions, with the final session involving a review and ending of the intervention.

2.5. Analysis

Feasibility and acceptability results are reported descriptively. Clinical outcomes were analysed on an intention-to-treat basis using all available data. Missing cases were treated as missing at random with a small number of individual missing data points (<5%) imputed using an expectation-maximization method and multiple imputation used for the three missing outcome cases (pooled aggregate of 50 iterations; Enders, 2001; Tabachnick and

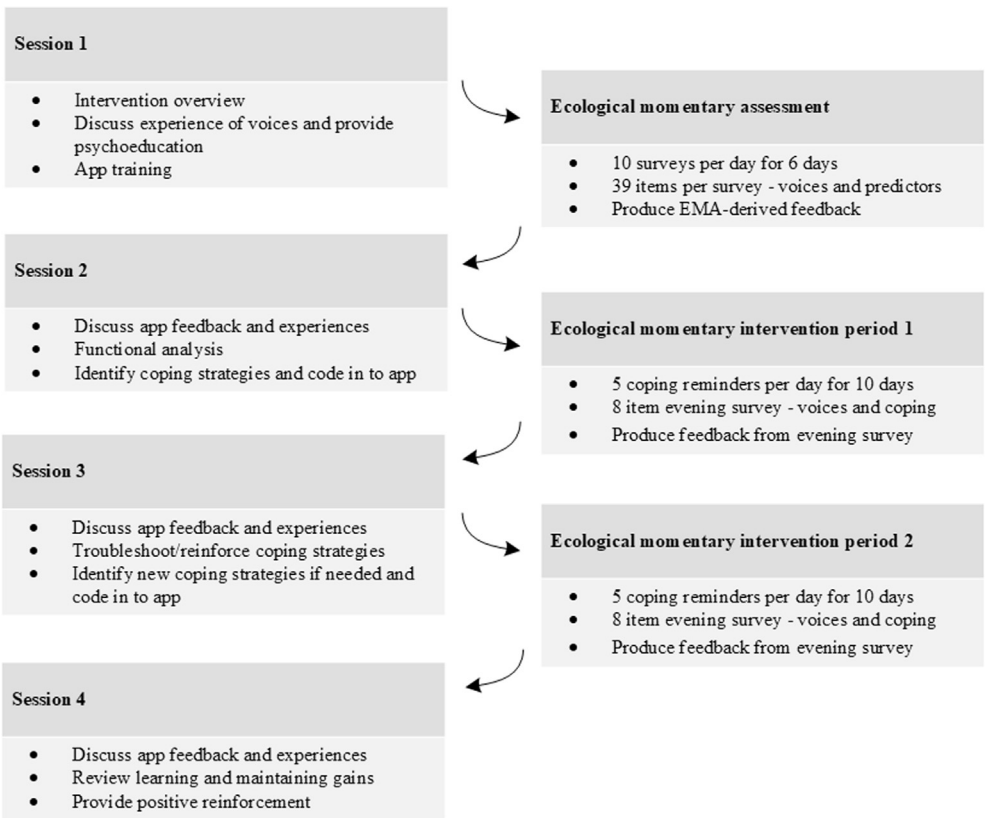

Fig. 1. Intervention procedure.

Please cite this article as: Bell, I.H et al., Pilot randomised controlled trial of a brief coping-focused intervention for hearing voices blended with smartphone-based ecological momentary assessment and intervention (SAVVy): Feasibility, acceptability and preliminary clinical outcomes, Schizophrenia Research, https://doi.org/10.1016/j.schres.2019.10.026

Table 1
Demographic and Clinical Characteristics of each group.

Variable	SAVVy + TAU ($n = 17$)	TAU ($n = 17$)
Age *M*(*SD*)	39.12 (10.64)	42.59 (10.64)
Gender (%Female)	64.7%	47.1%
Marital status *n*(%)		
Single	70.6%	64.7%
Divorced	5.9%	17.6%
Defacto	5.9%	11.8%
Married	5.9%	0%
Separated	11.8%	0%
Country of birth *n*(%)		
Australia	76.5%	82.4%
Central/South America	0%	5.9%
UK or Europe	5.9%	0%
New Zealand	5.9%	0%
India or Asia Subcontinent	5.9%	5.9%
South East Asia	0%	5.9%
Middle East	5.9%	0%
Ethnicity *n*(%)		
Australian	70.6%	94.1%
New Zealander	5.9%	0%
British or Irish	11.6%	0%
Greek	5.9%	5.9%
Other	5.9%	0%
Primary language *n*(%)		
English	100%	100%
Level of education *n*(%)		
Year 10 or less	11.8%	23.5%
Year 11/12	41.2%	17.6%
Diploma	17.6%	23.5%
Bachelor's degree	17.6%	23.5%
Post graduate diploma/Graduate Certificate	0%	5.9%
Current employment *n*(%)		
Employed full time	5.9%	11.8%
Employed part time	0%	11.8%
Casually employed	11.8%	11.8%
Unemployed	41.2%	47.1%
Student	29.4%	5.9%
Volunteer	0%	11.8%
Home duties	11.8%	0%
Primary diagnosis *n*(%)		
Bipolar Disorder w psychotic feat.	11.8%	17.7%
Major Depression w psychotic feat.	0%	5.9%
Schizoaffective Disorder	29.4%	47.1%
Schizophrenia	52.9%	23.5%
Schizophreniform	0%	5.9%
Unspecified Schizophrenia Spectrum Disorder	5.9%	0%
SANS *M*(*SD*)	8.82 (6.36)*	17.58 (11.21)*
Chlorpromazine equivalence *M*(*SD*)	519.06 (419.97)	296.73 (385.29)
WTAR *M*(*SD*)	103.35 (14.45)	99.18 (8.61)
Owns a smartphone *n*(%)	94.1%	70.6%
Has internet access *n*(%)	97%	100%
Use of internet (median)	More than once per day (58.8%)	More than once per day (47.1%)
Confidence using apps *M*(*SD*)[a]	5.76 (1.79)	4.06 (2.28)

Note: *significant difference between groups; [a]Confidence using apps was measured on a 7-point Likert type scale from 1(*very unconfident*) to 7(*very confident*).

Fidell, 2007). Clinical outcomes are presented as pooled means and standard deviations, with Hedges' *g* formula used to calculate standardised effect sizes and associated 95% confidence intervals (Durlak, 2009). Effect sizes for all variables were coded so that positive values reflected changes favouring the treatment group. In line with our planned analysis, analysis of covariance (ANCOVA) was used to test for differences between treatment and control group scores on all clinical outcome and process measures at the outcome timepoint, controlling for baseline scores. For the two ordinal measures of frequency and number of coping strategies used, Wilcoxon Sign Ranks Test were used to compare pre-post changes within each group. All outcome analyses were conducted using IBM SPSS Statistics Version 25 (SPSS Inc, 2017). EMA and EMI feasibility statistics and EMA-derived feedback analysis within the intervention were conducted using Stata Version 14.1 (StataCorp, 2015).

3. Results

3.1. Sample characteristics

Demographic and clinical characteristics of both groups are provided in Table 1. Group comparisons revealed significantly higher SANS scores in the control compared to treatment group ($F(1,32) = 7.86$, $p < .01$), with no other differences identified.

3.2. Feasibility

Fig. 2 displays the CONSORT flow diagram. Of those screened for eligibility, there was a 34% uptake into the trial. Data were available for 31 (91%) participants at post-treatment, with 3 participants lost to follow-up (2 control, 1 treatment) and no withdrawals. Of the 17 participants in the treatment group, 13 completed all four sessions.

Please cite this article as: Bell, I.H et al., Pilot randomised controlled trial of a brief coping-focused intervention for hearing voices blended with smartphone-based ecological momentary assessment and intervention (SAVVy): Feasibility, acceptability and preliminary clinical outcomes, Schizophrenia Research, https://doi.org/10.1016/j.schres.2019.10.026

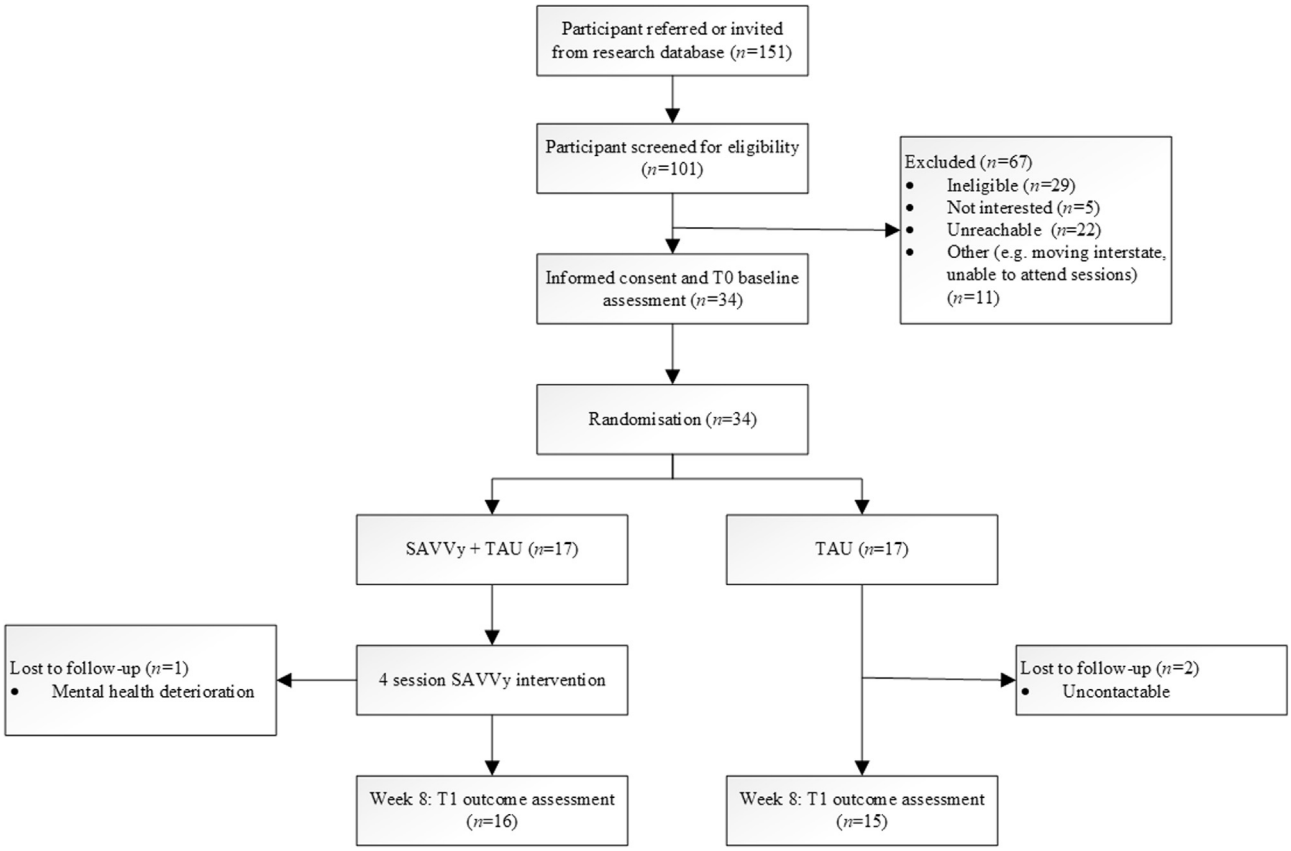

Fig. 2. CONSORT flow diagram.

Two stated they could no longer find time for participation (one attending three sessions and the other one session), and the two remaining participants discontinued sessions due to worsening in mental health precluding their ability to attend appointments (one attending three sessions and the other one session). These reasons were judged as factors external to the trial and unrelated to the intervention. Group comparisons did not reveal any significant differences between those who did and did not drop out on any demographic or clinical variables, or confidence using smartphones ($p > .05$). Ninety percent of therapy checklist items were endorsed as completed across the four sessions.

Two participants discontinued therapy during the EMA monitoring period, and another experienced a technological issue with the smartphone alerts, and was therefore excluded from EMA/I completion analysis. Across the remaining 14 participants, the average completion rate of the daytime EMA questionnaires was 72%. One-hundred percent of participants reached the minimum 33% completion rate criteria necessary to produce the EMA-derived feedback. Unplanned Pearson's correlation analyses did not reveal any significant relationships ($p > .05$) between completion rates and confidence in using smartphone apps, demographic or clinical variables, or clinical outcome variables. Completion rates of evening EMA questionnaires across the intervention was 74%. Scheduled EMI reminders were viewed on average 2.5 times per day, and 1.5 times per day when user-initiated (one participant was excluded due to technical issues resulting in additional EMI reminders).

3.3. Acceptability

Table 2 displays the average responses to each item of the satisfaction questionnaire. Overall, responses reflected good satisfaction across all elements of the intervention, with 100% of treatment group participants agreeing that they would recommend it to other people who hear voices. Open feedback was minimal, but largely positive, with all verbatim responses displayed in Table 3. The average WAI-SR item score (range 1–5) was 4.33 (SD = 0.55), suggesting that participants developed positive working alliances with the therapist. The average CEQ scores of the 3-item Credibility subscale (range 1–9) were 7.5 (S = 1.56) for the perceived logic of the therapy, 6.68 (SD = 1.53) for the perceived success of the therapy, and 6.56 (SD = 2.21) for the confidence in recommending the therapy to others. Mean scores on the CEQ and WAI-SR were similar to those reported in other trials in analogous populations (Gaudiano et al., 2015; Webb et al., 2013; White et al., 2011).

3.4. Clinical outcomes

Scores on all clinical outcome and process measures for both groups at baseline and outcome timepoints are displayed in Table 4. Moderate effect sizes favouring the treatment group were observed for PSYRATS-AH total score with a trend towards significant difference between groups ($F(1,31) = 3.00$, $p = .09$). Small, non-significant effects favouring the treatment group for the SEPS negative impact subscale ($F(1,31) = 0.55$, $p = .46$), and very small, non-significant effects favouring the control group on DASS-21 scores ($F(1,31) = 1.87$, $p = .18$), were observed. A very large effect favouring the treatment group was observed for the VAS coping with voices item and differences between groups were significant ($F(1,31) = 23.59$, $p < .001$). Similarly, the VAS awareness of patterns in voices item was also significantly different between groups ($F(1,31) = 5.40$, $p < .05$), with a moderate effect size. Analyses with significant group differences were run again with SANS as an additional covariate. Group differences for the VAS coping with

Please cite this article as: Bell, I.H et al., Pilot randomised controlled trial of a brief coping-focused intervention for hearing voices blended with smartphone-based ecological momentary assessment and intervention (SAVVy): Feasibility, acceptability and preliminary clinical outcomes, Schizophrenia Research, https://doi.org/10.1016/j.schres.2019.10.026

Table 2
Means and standard deviations of item responses to the satisfaction survey.

Item and range	M	SD
1(*strongly disagree*) to 5(*strongly agree*)		
1. Overall, the smartphone app was easy to use	4.43	0.94
2. Monitoring my voice/s using the app helped me to understand more about these experiences	4.21	0.70
3. The questions in the app were easy to understand	4.50	0.65
4. The coping strategy reminders were useful to help me cope with my voice/s	4.29	0.61
5. It was useful to discuss the smartphone feedback in therapy	4.57	0.51
6. The feedback about the coping strategies was useful	4.50	0.65
7. The feedback about patterns in my voice/s was helpful in understanding my experiences	4.43	0.65
8. I found the therapy helpful overall	4.50	0.65
9. I would recommend this intervention to other people with voice-hearing experiences	4.64	0.50
1(*not often enough*) to 5(*too often*)		
10. The number of beeps from the app were …	3.36	0.84
11. The number of coping strategy reminders from the app were …	3.21	0.58
1(*not enough*) to 5(*too many*)		
12. The number of sessions were …	3.21	0.58

Table 3
Verbatim open feedback from participants.

Negative	Positive
Just the problems with the phone and the app in the second stage. Became a bit tedious.[a]	Thanks to this study I now realise I can have a better and more happy, stress-free and peaceful life if I can take a good look objectively at the experience of the voices and work out some constructive ways of dealing with them.
The initial number of prompts in the first week was a little annoying.	It helped me to control my voices and to make me feel better about myself.
It required a lot of time and effort. Which is okay but its been a busy time of the year for the first time in many years and I found it hard to focus on everything and keep up.[b]	It helped me to make a connection between the voices and my own thoughts and feelings. It reminded me to take care of myself.
Discussing what I am talking, getting confused at times about my past.	Identifying triggers and patterns was helpful in terms of understanding my voices, how to cope with them, and the discussion I had with the therapist.
When it beeped at inappropriate times, middle of writing an email or at church.	I could talk about the voices and they could understand how I was feeling.
	Collaboratively exploring new ways to understand my negative self-sabotaging voice and how it can and does affect me in daily activities.
	Good to discuss what I experience with someone who understands.
	I tended to be able to notice when the voices were getting worse or better.
	A good reminder about time passing, to eat, do something.
	Detecting patterns in the voices.
	There was nothing I didn't like, it was all good and I had the support to cope with the voices.

[a] participant experienced a technical issue with the smartphone app.
[b] participant dropped out due to conflicting study and work commitments during the trial.

Table 4
Summary statistics and effects on clinical measures for each group.

	SAVVy + TAU ($n = 17$)		TAU ($n = 17$)		Hedges *g*	95% Confidence Intervals
Measure	Baseline Mean (SD)	Outcome Mean (SD)	Baseline Mean (SD)	Outcome Mean (SD)		
PSYRATS Total	28.47 (4.87)	25.89 (6.37)	28.76 (4.41)	29.47 (6.45)	0.55	−0.14, 1.23
SEPS Negative Impact Subscale	91.24 (28.03)	83.08 (26.00)	95.88 (23.44)	90.59 (22.53)	0.30	−0.37, 0.98
DASS-21 Overall	58.24 (32.77)	65.61 (28.30)	65.88 (32.14)	60.11 (31.88)	−0.18	−0.85, 0.50
Coping items						
1. Confidence in coping	56.00 (30.83)	65.77 (21.90)	55.76 (23.02)	33.24 (22.05)	1.45***	0.69, 2.20
2. Understanding of voices	53.53 (33.40)	72.63 (23.03)	53.18 (27.37)	56.39 (28.35)	0.61**	−0.07, 1.30
	Median (IQR)	Median (IQR)	Median (IQR)	Median (IQR)		
3. Frequency of coping strategy use*	3 (2–4)	4 (3–4)	3 (2–4)	2 (2–4)		
4. Number of coping strategies*	2 (2–3)	3 (3–4)	1 (2–3)	2 (2–3)		

Note. Means and standard deviations incorporate pooled imputations; ***$p < .001$; **$p < .01$; *$p < .05$.

voices item remained significant (($F(1,30) = 27.03$, $p < .001$), but was no longer significant for the VAS awareness of patterns in voices item ($F(1,30) = 2.90$, $p = .09$). Wilcoxon Signed Ranks tests indicated a marginally significant pre-post increase in the number of coping strategies ($Z = -1.89$, $p = .06$), but not the frequency of their use ($Z = -0.37$, $p = .71$), in the treatment group. There were no changes in the control group on the number of coping strategies ($Z = -0.36$, $p = .72$) nor frequency of their use ($Z = -0.24$, $p = .81$). Unplanned Pearson's correlations were run to examine whether confidence in using smartphone apps was related to any scores on

Please cite this article as: Bell, I.H et al., Pilot randomised controlled trial of a brief coping-focused intervention for hearing voices blended with smartphone-based ecological momentary assessment and intervention (SAVVy): Feasibility, acceptability and preliminary clinical outcomes, Schizophrenia Research, https://doi.org/10.1016/j.schres.2019.10.026

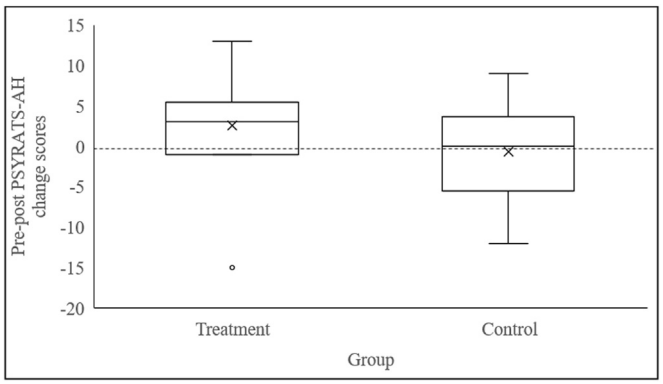

Fig. 3. Pre-post change scores on PSYRATS-AH for treatment and control groups.

clinical or process measures within the treatment group at the outcome time point, with none reaching significance ($p > .05$). Sensitivity analyses were conducted which revealed minimal differences in the above analyses between imputed and non-imputed data sets (Thabane et al., 2013).

Fig. 3 displays box plots of PSYRATS-AH change scores in each group. There was an outlier in the treatment group representing a pre-post increase (i.e. worsening) in PSYRATS-AH total score. A review of assessment recordings and a follow-up qualitative interview indicated this was likely to be due to an external life event occurring around the time of the outcome assessment. A sensitivity analysis excluding this individual resulted in the effect on PSYRATS-AH becoming significant [$(F(1,30) = 6.36,\ p < .05$; Hedges $g = 0.61$, 95% CI $= -0.07,1.33$], with other results remaining the same.

3.5. Adverse events

Two events classed as serious adverse events (hospital admissions) according to the Australian National Health & Medical Research Council ([NHMRC], 2007) were reported—one from the treatment group and other from control. A review concluded these were unrelated to the trial or intervention.

4. Discussion

The findings of this study support the feasibility and acceptability of a brief coping-focused intervention for distressing voice-hearing experiences which blended standard face-to-face psychological therapy with EMA/I between session. Completion rates of the EMA questionnaires were high, leading to the production of EMA-derived feedback in all attempted cases, and there was good engagement with both prompted and user-initiated EMI coping reminders. Despite minor technological issues, feedback regarding different aspects of the intervention was largely positive. These findings extend digital mental health research in psychosis by demonstrating that smartphone technologies can support standard face-to-face therapies; otherwise known as *blended therapy* (Erbe et al., 2017).

Research has demonstrated that EMI can support independent self-management of psychosis (Bell et al., 2017; Bucci et al., 2018; Schlosser et al., 2018). Our findings suggest that personalised EMI reminders of tailored self-management strategies determined during therapy may support the generalisation of these strategies into daily life. Participants were engaged with these EMI reminders and feedback suggested they were helpful. It is conceivable that personalised EMI reminders may be a simple and useful technology for other psychological treatment approaches. Future developments may involve more streamlined programming of EMI content and the use of context-aware systems to determine the timing and nature of tailored EMI prompts (Bakker et al., 2016; Burns et al., 2011; Price et al., 2014; Proudfoot, 2013).

A significant novelty of this study is the analysis of within-person EMA data to inform clinical formulation in psychological therapy. No other study has examined this application of EMA in psychosis, despite considerable interest (Ebner-Priemer and Trull, 2009; Firth and Torous, 2015; McDevitt-Murphy et al., 2018; Myin-Germeys et al., 2016; Oorschot et al., 2012; Trull and Ebner-Priemer, 2009). Although one case experienced a technological issue whereby the alerts were not consistently received, the overall high completion rate of the EMA questionnaires led to the production of EMA-derived feedback in all attempted cases. This, alongside predominantly positive feedback from participants, supports the feasibility and acceptability of this approach. The high level of engagement with both EMA and EMI components are consistent with other similar studies (Ben-Zeev et al., 2014; Berkel et al., 2017; Bucci et al., 2018; Firth and Torous, 2015; Kumar et al., 2018), although recent findings suggest naturalistic engagement with apps may be lower (Torous et al., 2017). Notably, one participant who dropped out commented on the effort involved in the intervention, suggesting this approach may be more difficult for those with limited time. Whilst we did not find evidence of a relationship between the characteristics of the sample and engagement with, nor effects of, the intervention, further research in this area would be beneficial to identify what works best and for whom (Michie et al., 2017; Ritterband et al., 2006).

It is hoped that this study, being the first of its kind, spurs further research exploring different statistical and methodological approaches to conducting within-person analysis of EMA data for clinical purposes. We used regression analyses and summary statistics, however other statistical approaches, such as network analysis (Bringmann et al., 2013), machine learning (Burns et al., 2011) or dynamic factor modelling (Fisher, 2015), may also be appropriate (Barnett et al., 2018; Myin-Germeys et al., 2016). Automated analyses which produce simple, accurate, meaningful and engaging data visualisations, possibly in real time, would also be beneficial. Further research should also explore the most appropriate EMA sampling schedule for different clinical purposes and the development of validated EMA scales (Firth and Torous, 2015).

Although only a pilot trial, post-intervention effects were in a direction favouring the treatment group for the primary clinical outcome of overall severity of voices, and to a lesser extent the secondary outcome of negative impact of the voices, but not emotional distress. More proximal, process, measures indicated statistically significant improvements favouring the treatment group in confidence in coping with voices, awareness of factors influencing voices, and close to significant increase in the number (but not frequency) of coping strategies used. These findings suggest this intervention holds promise for reducing the overall severity of voices and their negative impact, possibly occurring via the process of improved coping and understanding of voices. The very large effects observed on the measure of confidence in coping with voices provides proof-of-concept evidence for the mechanisms of the intervention. As these processes were targeted directly by EMA/I, this suggests the technology component was of benefit. These effects appear consistent with prior trials of CSE-based interventions (Hayward et al., 2018; Paulik et al., 2018; Tarrier et al., 1993, 1998; Yusupoff and Tarrier, 1996), however direct comparisons are limited due to variations in methodology. Notably, one participant within the treatment group showed a worsening in the primary outcome measure which may have lowered our conservative estimate of the average effect size. Whilst our investigation suggested an external life event was the main contributing factor,

Please cite this article as: Bell, I.H et al., Pilot randomised controlled trial of a brief coping-focused intervention for hearing voices blended with smartphone-based ecological momentary assessment and intervention (SAVVy): Feasibility, acceptability and preliminary clinical outcomes, Schizophrenia Research, https://doi.org/10.1016/j.schres.2019.10.026

this highlights caution in ensuring adverse events are considered in any larger scale trialling, an area possibly neglected in CBT for psychosis research (Morrison, 2018).

The following limitations should be recognised. Firstly, it is unclear if the effects of the intervention were maintained as there was no follow-up time-point. Secondly, the intervention contained multiple components, limiting inferences regarding specific therapeutic mechanisms. A future trial should carefully consider an active comparison group (e.g., Bucci et al., 2018), including the recently highlighted *digital placebo effect* (Torous and Firth, 2016). Dismantling studies to isolate the active ingredients of digital interventions may assist in refining the features which yield maximum benefits, whilst improving our understanding of the mechanisms which drive them (Collins et al., 2007; Michie et al., 2017). Thirdly, the small sample size limits generalisability and clearly a fully powered trial is needed to determine clinical efficacy. Fourth, group difference in negative symptoms at baseline were observed, however it is noted that subsequent analyses controlling for this variable resulted in only minor changes.

Conclusion

The current study demonstrates the clinical potential of EMA/I as tools within blended therapies for psychotic experiences. This justifies potential further development of a purpose-built mobile app with evaluation in a full scale RCT to determine efficacy, and potentially investigations within other psychological treatment approaches and clinical populations.

Declaration of competing interest

The authors declare there are no conflicts of interest.

Acknowledgments

The authors thank the participants, lived experience consultants, and researchers Professor Denny Meyer, Dr Wei Lin Toh, Dr Rachel Brand, Ms Inge Gnatt and Ms Louise Moncur.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.schres.2019.10.026.

Contributors

IHB and NT conceptualised the intervention. IHB led the design of the protocol, with contributions from all other authors. IHB conducted the trial, with oversight by NT. SLR and NT assisted with the analysis, which was conducted by IHB. IHB wrote the first draft of this manuscript, with contributions from all other authors. All authors contributed to and have approved the final manuscript.

Funding

This research was supported by the Australian Government Research Training Program Scholarship and the Barbara Dicker Brain Sciences Foundation Grant Scheme.

References

Alvarez-Jimenez, M., Alcazar-Corcoles, M., Gonzalez-Blanch, C., Bendall, S., McGorry, P., Gleeson, J., 2014. Online, social media and mobile technologies for psychosis treatment: a systematic review on novel user-led interventions. Schizophr. Res. 156 (1), 96–106.

Andreasen, N.C., 1989. Scale for the assessment of negative symptoms (SANS). Br. J. Psychiatry 155 (Suppl 7), 53–58.

Bakker, D., Kazantzis, N., Rickwood, D., Rickard, N., 2016. Mental health smartphone apps: review and evidence-based recommendations for future developments. JMIR Mental Health 3 (1).

Barnett, I., Torous, J., Staples, P., Keshavan, M., Onnela, J.P., 2018. Beyond smartphones and sensors: choosing appropriate statistical methods for the analysis of longitudinal data. J. Am. Med. Inform. Assoc. 25 (12), 1669–1674.

Bell, I.H., Lim, M.H., Rossell, S.L., Thomas, N., 2017. Ecological momentary assessment and intervention in the treatment of psychotic disorders: a systematic review. Psychiatr. Serv. 68 (11), 1172–1181.

Bell, I.H., Fielding-Smith, S.F., Hayward, M., Rossell, S.L., Lim, M.H., Farhall, J., Thomas, N., 2018a. Smartphone-based ecological momentary assessment and intervention in a blended coping-focused therapy for distressing voices: development and case illustration. Internet Interventions 14, 18–25. https://doi.org/10.1016/j.invent.2018.11.001.

Bell, I.H., Fielding-Smith, S.F., Hayward, M., Rossell, S.L., Lim, M.H., Farhall, J., Thomas, N., 2018b. Smartphone-based ecological momentary assessment and intervention in a coping-focused intervention for hearing voices (SAVVy): study protocol for a pilot randomised controlled trial. Trials 19 (1), 262. https://doi.org/10.1186/s13063-018-2607-6.

Ben-Zeev, D., Brenner, C.J., Begale, M., Duffecy, J., Mohr, D.C., Mueser, K.T., 2014. Feasibility, acceptability, and preliminary efficacy of a smartphone intervention for schizophrenia. Schizophr. Bull. 40 (6), 1244–1253.

Berkel, N.V., Ferreira, D., Kostakos, V., 2017. The experience sampling method on mobile devices. ACM Comput. Surv. 50 (6), 93.

Berry, K., Haddock, G., 2008. The implementation of the NICE guidelines for schizophrenia: barriers to the implementation of psychological interventions and recommendations for the future. Psychol. Psychother. Theory Res. Pract. 81 (4), 419–436.

Brenner, C., Ben-Zeev, D., 2014. Affective forecasting in schizophrenia: comparing predictions to real-time Ecological Momentary Assessment (EMA) ratings. Psychiatr. Rehabil. J. 37 (4), 316.

Bringmann, L.F., Vissers, N., Wichers, M., Geschwind, N., Kuppens, P., Peeters, F., et al., 2013. A network approach to psychopathology: new insights into clinical longitudinal data. PLoS One 8 (4), e60188.

Bucci, S., Barrowclough, C., Ainsworth, J., Machin, M., Morris, R., Berry, K., et al., 2018a. Actissist: proof-of-concept trial of a theory-driven digital intervention for psychosis. Schizophrenia Bulletin, p. sby032.

Bucci, S., Morris, R., Berry, K., Berry, N., Haddock, G., Barrowclough, C., et al., 2018b. Early psychosis service user views on digital technology: qualitative analysis. JMIR Mental Health 5 (4), e10091.

Burns, M.N., Begale, M., Duffecy, J., Gergle, D., Karr, C.J., Giangrande, E., Mohr, D.C., 2011. Harnessing context sensing to develop a mobile intervention for depression. JMIR 13 (3), e55.

Collins, L.M., Murphy, S.A., Strecher, V., 2007. The multiphase optimization strategy (MOST) and the sequential multiple assignment randomized trial (SMART): new methods for more potent eHealth interventions. Am. J. Prev. Med. 32 (5), S112–S118.

Delespaul, P., 1995. Assessing Schizophrenia in Daily Life – the Experience Sampling *Method.* Maastricht. IPSER Foundation, Netherlands.

Devilly, G.J., Borkovec, T.D., 2000. Psychometric properties of the credibility/expectancy questionnaire. J. Behav. Ther. Exp. Psychiatry 31 (2), 73–86.

Dixon, L.B., Holoshitz, Y., Nossel, I., 2016. Treatment engagement of individuals experiencing mental illness: review and update. World Psychiatry 15 (1), 13–20.

Durlak, J.A., 2009. How to select, calculate, and interpret effect sizes. J. Pediatr. Psychol. 34 (9), 917–928.

Ebner-Priemer, U.W., Trull, T.J., 2009. Ambulatory assessment: an innovative and promising approach for clinical psychology. Eur. Psychol. 14 (2), 109–119.

Enders, C.K., 2001. A primer on maximum likelihood algorithms available for use with missing data. Struct. Equ. Model. 8 (1), 128–141.

Erbe, D., Eichert, H.-C., Riper, H., Ebert, D.D., 2017. Blending face-to-face and internet-based interventions for the treatment of mental disorders in adults: systematic review. JMIR 19 (9).

Farhall, J., Thomas, N., 2013. Cognitive and behavioural therapies for psychosis. Aust. N. Z. J. Psychiatr. 47 (6), 508–511. https://doi.org/10.1177/0004867413483370.

Fioravanti, M., Bianchi, V., Cinti, M.E., 2012. Cognitive deficits in schizophrenia: an updated metanalysis of the scientific evidence. BMC Psychiatry 12 (1), 64.

First, M.B., Williams, J.B.W., Karg, R.S., Spitzer, R.L., 2015. Structured Clinical Interview for DSM-5—Research Version (SCID-5 for DSM-5, Research Version; SCID-5-RV). American Psychiatric Association, Arlington, VA.

Firth, J., Torous, J., 2015. Smartphone apps for schizophrenia: a systematic review. JMIR mHealth and uHealth 3 (4), e102.

Firth, J., Cotter, J., Torous, J., Bucci, S., Firth, J.A., Yung, A.R., 2015. Mobile phone ownership and endorsement of "mHealth" among people with psychosis: a meta-analysis of cross-sectional studies. Schizophr. Bull. 42 (2), 448–455.

Fisher, A.J., 2015. Toward a dynamic model of psychological assessment: implications for personalized care. J. Consult. Clin. Psychol. 83 (4), 825.

Galletly, C., Castle, D., Dark, F., Humberstone, V., Jablensky, A., Killackey, E., et al., 2016. Royal Australian and New Zealand College of Psychiatrists clinical practice guidelines for the management of schizophrenia and related disorders. Aust. N. Z. J. Psychiatr. 50 (5), 410–472.

Gaudiano, B.A., Busch, A.M., Wenze, S.J., Nowlan, K., Epstein-Lubow, G., Miller, I.W., 2015. Acceptance-based behavior therapy for depression with psychosis: results from a pilot feasibility randomized controlled trial. J. Psychiatr. Pract. 21 (5), 320.

Gay, K., Torous, J., Joseph, A., Pandya, A., Duckworth, K., 2016. Digital technology use

among individuals with schizophrenia: results of an online survey. JMIR Mental Health 3 (2).
Granholm, E., Loh, C., Swendsen, J., 2008. Feasibility and validity of computerized ecological momentary assessment in schizophrenia. Schizophr. Bull. 34 (3), 507–514.
Haddock, G., McCarron, J., Tarrier, N., Faragher, E., 1999. Scales to measure dimensions of hallucinations and delusions: the psychotic symptom rating scales (PSYRATS). Psychol. Med. 29 (04), 879–889.
Haddock, G., Wood, L., Watts, R., Dunn, G., Morrison, A.P., Price, J., 2011. The Subjective Experiences of Psychosis Scale (SEPS): psychometric evaluation of a scale to assess outcome in psychosis. Schizophr. Res. 133 (1), 244–249.
Haddock, G., Eisner, E., Boone, C., Davies, G., Coogan, C., Barrowclough, C., 2014. An investigation of the implementation of NICE-recommended CBT interventions for people with schizophrenia. J. Ment. Health 23 (4), 162–165.
Hatcher, R.L., Gillaspy, J.A., 2006. Development and validation of a revised short version of the Working Alliance Inventory. Psychother. Res. 16 (1), 12–25.
Hayward, M., Edgecumbe, R., Jones, A.M., Berry, C., Strauss, C., 2018. Brief coping strategy enhancement for distressing voices: an evaluation in routine clinical practice. Behav. Cognit. Psychother. 46 (2), 226–237.
Hazell, C.M., Hayward, M., Cavanagh, K., Jones, A.M., Strauss, C., 2018. Guided self-help cognitive-behaviour Intervention for VoicEs (GiVE): results from a pilot randomised controlled trial in a transdiagnostic sample. Schizophr. Res. 195, 441–447.
Heron, K., Smyth, J., 2010. Ecological momentary interventions: incorporating mobile technology into psychosocial and health behaviour treatments. Br. J. Health Psychol. 15 (1), 1–39.
Ince, P., Haddock, G., Tai, S., 2016. A systematic review of the implementation of recommended psychological interventions for schizophrenia: rates, barriers, and improvement strategies. Psychol. Psychother. Theory Res. Pract. 89 (3), 324–350.
Jauhar, S., McKenna, P., Radua, J., Fung, E., Salvador, R., Laws, K., 2014. Cognitive-behavioural therapy for the symptoms of schizophrenia: systematic review and meta-analysis with examination of potential bias. Br. J. Psychiatry 204 (1), 20–29.
Johansen, R., Hestad, K., Iversen, V.C., Agartz, I., Sundet, K., Andreassen, O.A., Melle, I., 2011. Cognitive and clinical factors are associated with service engagement in early-phase schizophrenia spectrum disorders. J. Nerv. Ment. Dis. 199 (3), 176–182.
Julious, S.A., 2005. Sample size of 12 per group rule of thumb for a pilot study. Pharm. Stat.: *The Journal of Applied Statistics in the Pharmaceutical Industry* 4 (4), 287–291.
Kumar, D., Tully, L.M., Iosif, A.-M., Zakskorn, L.N., Nye, K.E., Zia, A., Niendam, T.A., 2018. A mobile health platform for clinical monitoring in early psychosis: implementation in community-based outpatient early psychosis care. JMIR Mental Health 5 (1).
Lovibond, P.F., Lovibond, S.H., 1995. The structure of negative emotional states: comparison of the depression anxiety stress scales (DASS) with the beck depression and anxiety inventories. Behav. Res. Ther. 33 (3), 335–343.
McDevitt-Murphy, M.E., Luciano, M.T., Zakarian, R.J., 2018. Use of ecological momentary assessment and intervention in treatment with adults. Focus 16 (4), 370–375.
National Health and Medical Research Council, 2007. National statement on ethical conduct in human research 2007 (Updated May 2015). Retrieved from. https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007.
Michie, S., Yardley, L., West, R., Patrick, K., Greaves, F., 2017. Developing and evaluating digital interventions to promote behavior change in health and health care: recommendations resulting from an international workshop. JMIR 19 (6).
Morrison, A.P., 2018. Should people with psychosis be supported in choosing cognitive therapy as an alternative to antipsychotic medication: a commentary on current evidence. Schizophrenia Research.
MovisensXS. Retrieved from. https://xs.movisens.com/.
Myin-Germeys, I., Klippel, A., Steinhart, H., Reininghaus, U., 2016. Ecological momentary interventions in psychiatry. Curr. Opin. Psychiatr. 29 (4), 258–263.
National Institute for Health and Care Excellence [NICE], 2010. Core Interventions in the Treatment and Mangement of Schizophrenia in Adults in Primary and Secondary Care, updated edition. UK The British Psychological Society and The Royal College of Psychiatrists, London.
Oorschot, M., Lataster, T., Thewissen, V., Wichers, M., Myin-Germeys, I., 2012. Mobile assessment in schizophrenia: a data-driven momentary approach. Schizophr. Bull. 38 (3), 405–413.
Palmier-Claus, J.E., Ainsworth, J., Machin, M., Barrowclough, C., Dunn, G., Barkus, E., et al., 2012. The feasibility and validity of ambulatory self-report of psychotic symptoms using a smartphone software application. BMC Psychiatry 12 (1), 172.
Palmier-Claus, J., Myin-Germeys, I., Barkus, E., Bentley, L., Udachina, A., Delespaul, P., et al., 2011. Experience sampling research in individuals with mental illness: reflections and guidance. Acta Psychiatr. Scand. 123 (1), 12–20.
Paulik, G., Jones, A.M., Hayward, M., 2018. Brief coping strategy enhancement for distressing voices: P redictors of engagement and outcome in routine clinical practice. Clin. Psychol. Psychother. 25 (5), 634–640.
Price, M., Yuen, E.K., Goetter, E.M., Herbert, J.D., Forman, E.M., Acierno, R., Ruggiero, K.J., 2014. mHealth: a mechanism to deliver more accessible, more effective mental health care. Clin. Psychol. Psychother. 21 (5), 427–436.
Proudfoot, J., 2013. The future is in our hands: the role of mobile phones in the prevention and management of mental disorders. Aust. N. Z. J. Psychiatr. 47 (2), 111–113. https://doi.org/10.1177/0004867412471441.
QMinim. Retrieved from http://qminim.sourceforge.net.
Ritterband, L.M., Andersson, G., Christensen, H.M., Carlbring, P., Cuijpers, P., 2006. Directions for the international society for research on internet interventions (ISRII). JMIR 8 (3).
Schizophrenia Commission, T.S., 2012. The Abandoned Illness: a Report from the Schizophrenia Commission. Illness RM, London.
Schlosser, D.A., Campellone, T.R., Truong, B., Etter, K., Vergani, S., Komaiko, K., Vinogradov, S., 2018. Efficacy of PRIME, a mobile app intervention designed to improve motivation in young people with schizophrenia. Schizophr. Bull. 44 (5), 1010–1020.
Sheehan, D.V., Lecrubier, Y., Sheehan, K.H., Amorim, P., Janavs, J., Weiller, E., et al., 1998. The Mini-International Neuropsychiatric Interview (MINI): the development and validation of a structured diagnostic psychiatric interview for DSM-IV and ICD-10. J. Clin. Psychiatry 59 (Suppl 20), 22–33.
Shiffman, S., Stone, A., Hufford, M., 2008. Ecological momentary assessment. Annu. Rev. Clin. Psychol. 4, 1–32.
Sim, J., Lewis, M., 2012. The size of a pilot study for a clinical trial should be calculated in relation to considerations of precision and efficiency. J. Clin. Epidemiol. 65 (3), 301–308.
SPSS Inc, 2017. IBM SPSS Statistics for Windows (Version. IBM Corp, Armonk, NY, version 25.0.
StataCorp, 2015. Stata Statistical Software: Release 14. StataCorp LP, College Station, TX.
Stone, A., Shiffman, S., Atienza, A., Nebeling, L., 2007. The Science of Real-Time Data Capture: Self-Reports in Health Research. Oxford University Press.
Tabachnick, B.G., Fidell, L.S., 2007. Using Multivariate Statistics, fifth ed. Allyn & Bacon/Pearson Education, Boston, USA.
Tarrier, N., 1992. Management and modification of residual positive psychotic symptoms. In: Birchwood, M., Tarrier, N. (Eds.), Innovations in the Psychological Management of Schizophrenia: Assessment, Treatment and Services. Wiley Series in Clinical Psychology, pp. 147–169.
Tarrier, N., Harwood, S., Yusopoff, L., Beckett, R., Baker, A., 1990. Coping strategy enhancement (CSE): a method of treating residual schizophrenic symptoms. Behav. Psychother. 18 (04), 283–293.
Tarrier, N., Beckett, R., Harwood, S., Baker, A., Yusupoff, L., Ugarteburu, I., 1993. A trial of two cognitive-behavioural methods of treating drug-resistant residual psychotic symptoms in schizophrenic patients: I. Outcome. Br. J. Psychiatry 162 (4), 524–532.
Tarrier, N., Yusupoff, L., Kinney, C., McCarthy, E., Gledhill, A., Haddock, G., Morris, J., 1998. Randomised controlled trial of intensive cognitive behaviour therapy for patients with chronic schizophrenia. BMJ 317 (7154), 303–307.
Teare, M.D., Dimairo, M., Shephard, N., Hayman, A., Whitehead, A., Walters, S.J., 2014. Sample size requirements to estimate key design parameters from external pilot randomised controlled trials: a simulation study. Trials 15 (1), 1.
Thabane, L., Mbuagbaw, L., Zhang, S., Samaan, Z., Marcucci, M., Ye, C., et al., 2013. A tutorial on sensitivity analyses in clinical trials: the what, why, when and how. BMC Med. Res. Methodol. 13 (1), 92.
Thomas, N., Bless, J.J., Alderson-Day, B., Bell, I.H., Cella, M., Craig, T., et al., 2019. Potential applications of digital technology in assessment, treatment, and self-help for hallucinations. Schizophr. Bull. 45 (Suppl. ment_1), S32–S42.
Torous, J., Firth, J., 2016. The digital placebo effect: mobile mental health meets clinical psychiatry. The Lancet Psychiatry 3 (2), 100–102.
Torous, J., Friedman, R., Keshavan, M., 2014. Smartphone ownership and interest in mobile applications to monitor symptoms of mental health conditions. JMIR mHealth and uHealth 2 (1), e2.
Torous, J., Staples, P., Slaters, L., Adams, J., Sandoval, L., Onnela, J., Keshavan, M., 2017. Characterizing smartphone engagement for schizophrenia: results of a naturalist mobile health study. Clin. Schizophrenia Relat. Psychoses. In-Press. [Epub ahead of print].
Treisman, G.J., Jayaram, G., Margolis, R.L., Pearlson, G.D., Schmidt, C.W., Mihelish, G.L., et al., 2016. Perspectives on the use of eHealth in the management of patients with schizophrenia. J. Nerv. Ment. Dis. 204 (8), 620.
Trull, T., Ebner-Priemer, U., 2009. Using experience sampling methods/ecological momentary assessment (ESM/EMA) in clinical assessment and clinical research: introduction to the special section. Psychol. Assess. 21 (4), 457–462.
Turkington, D., Kingdon, D., Weiden, P.J., 2008. Cognitive behavior therapy for schizophrenia. Am. J. Psychiatry 6 (2), 257–266.
van der Gaag, M., Valmaggia, L.R., Smit, F., 2014. The effects of individually tailored formulation-based cognitive behavioural therapy in auditory hallucinations and delusions: a meta-analysis. Schizophr. Res. 156 (1), 30–37.
Webb, C.A., Kertz, S.J., Bigda-Peyton, J.S., Björgvinsson, T., 2013. The role of pre-treatment outcome expectancies and cognitive–behavioral skills in symptom improvement in an acute psychiatric setting. J. Affect. Disord. 149 (1–3), 375–382.
Wechsler, D., 2001. Wechsler Test of Adult Reading (WTAR). The Psychological Corporation, San Antonio, TX.
White, R., Gumley, A., McTaggart, J., Rattrie, L., McConville, D., Cleare, S., Mitchell, G., 2011. A feasibility study of Acceptance and Commitment Therapy for emotional dysfunction following psychosis. Behav. Res. Ther. 49 (12), 901–907.
Yusupoff, L., Tarrier, N., 1996. Coping strategy enhancement for persistent hallucinations and delusions. Cognitive-Behavioural Interventions with Psychotic Disorders 86–102.

Please cite this article as: Bell, I.H et al., Pilot randomised controlled trial of a brief coping-focused intervention for hearing voices blended with smartphone-based ecological momentary assessment and intervention (SAVVy): Feasibility, acceptability and preliminary clinical outcomes, Schizophrenia Research, https://doi.org/10.1016/j.schres.2019.10.026