Psychiatry Research 329 (2023) 115536

Contents lists available at ScienceDirect

Psychiatry Research

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

User engagement in a randomised controlled trial for a digital health intervention for early psychosis (Actissist 2.0 trial)

Lamiece Hassan [a], Emily Eisner [a,b], Katherine Berry [a,b], Richard Emsley [c], John Ainsworth [d], Shôn Lewis [a,b], Gillian Haddock [a,b], Dawn Edge [a,b], Sandra Bucci [a,b,*]

[a] Division of Psychology and Mental Health, School of Health Sciences, Manchester Academic Health Science Centre, The University of Manchester, Manchester, UK
[b] Research and Innovation, Greater Manchester Mental Health Foundation NHS Trust, Manchester, UK
[c] Department of Biostatistics and Health Informatics, Institute of Psychiatry, Psychology and Neuroscience, King's College London, London, UK
[d] Division of Informatics, Imaging and Data Sciences, School of Health Sciences, Manchester Academic Health Science Centre, The University of Manchester, Manchester, UK

ARTICLE INFO

Keywords:
m-health
RCT
Severe mental illness
Smartphone
Ecological momentary assessment
Digital mental health
Telepsychiatry
Psychosis

ABSTRACT

Digital Health Interventions (DHIs) can help support people with mental health problems. Achieving satisfactory levels of patient engagement is a crucial, yet often underexplored, pre-requisite for health improvement. Actissist is a co-produced DHI delivered via a smartphone app for people with early psychosis, based on Cognitive Behaviour Therapy principles. This study describes and compares engagement patterns among participants in the two arms of the Actissist 2.0 randomised controlled trial. Engagement frequency and duration were measured among participants using the Actissist app in the intervention arm (n = 87) and the ClinTouch symptom monitoring only app used as the control condition (n = 81). Overall, 47.1 % of Actissist and 45.7 % of ClinTouch users completed at least a third of scheduled alerts while active in the study. The mean frequency (77.1 versus 60.2 total responses) and the median duration (80 versus 75 days until last response) of engagement were not significantly higher among Actissist users compared to ClinTouch users. Older age, White ethnicity, using their own smartphone device and, among Actissist users, an increased sense of therapeutic alliance were significantly associated with increased engagement. Through exploiting detailed usage data, this study identifies possible participant-level and DHI-level predictors of engagement to inform the practical implementation of future DHIs.

1. Introduction

The growing field of digital mental health offers hope for transforming services using technological innovations to augment more conventional approaches to care. Increasingly, Digital Health Interventions (DHIs) - including mobile phone apps, websites and wearable devices - are being proposed as potentially low-cost, scalable solutions to improve and streamline the care of people with severe mental health problems, performing a wide range of functions including cognitive assessment, remote symptom monitoring, relapse prediction, therapy delivery and peer-to-peer support (Torous et al., 2021).

As well as understanding whether DHIs are safe, acceptable, bring clinical benefit, and can be implemented into clinical pathways, it is also important to discern how and when they work, and for whom. A precursor to achieving benefits, however, is that DHIs are accepted, accessed and used by people with severe mental health problems. In most cases, DHIs require at least some level of ongoing effort from patients – for example, actively submitting data, charging a battery, or simply carrying or wearing a device – engagement, therefore, is an important part of the equation for an effectively functioning DHI to achieve its intended outcomes. Yet, combating low levels of engagement with DHIs in the context of mental health has been identified as a key challenge (Nwosu et al., 2022; Torous et al., 2020).

Usage analyses have not yet become routinely reported in DHI studies and, where they do occur, may be lacking in standard definitions (Nwosu et al., 2022) and detail (Miller et al., 2019). While the concept of the 'law of attrition' in the context of e-health has usefully received some attention over recent years (Eysenbach, 2005), analyses of DHIs should not end at analysis of drop-out rates; by not harnessing the full extent of the available data, valuable opportunities for learning may be missed.

* Corresponding author at: Zochonis Building, Division of Psychology and Mental Health, School of Health Sciences, The University of Manchester, Manchester M13 9PL, UK.
E-mail address: sandra.bucci@manchester.ac.uk (S. Bucci).

https://doi.org/10.1016/j.psychres.2023.115536
Received 6 April 2023; Received in revised form 2 October 2023; Accepted 7 October 2023
Available online 8 October 2023
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For example, understanding both the frequency and the type of content users engage with could be valuable for optimising future interventions. Moreover, understanding relationships between engagement with DHIs and user characteristics could provide insight into equitability of access and whether DHIs are affected by the "digital divide" (Hardy et al., 2021). Indeed, while rates of mobile phone ownership among people with severe mental health problems may be comparable to the wider population (Firth et al., 2016), a significant proportion may lack essential digital skills, which could impede engagement with DHIs (Panagiotis et al., 2021).

Actissist is a co-produced DHI for people with early psychosis delivered via a smartphone app, based on Cognitive Behaviour Therapy (CBT) principles. The Actissist DHI is divided in two parts, although presented as a single app. The core CBT section of the app is titled 'what's bothering me' and targets five domains associated with early psychosis relapse (Alvarez-Jimenez et al., 2012) using a series of structured, self-assessment question-answer exchanges that focus on: perceived criticism; socialization; cannabis use; paranoia; and distressing voice-hearing. Users can also access multimedia content (e.g. videos, relaxation exercises, factsheets and web content), diary functions and customise the app aesthetics using their own images (Supplementary Fig. 1). Users are prompted to engage with treatment domains in the Actissist app via pseudo-random alerts. They can also self-initiate use by accessing the app and answering questions spontaneously. If a user accepts a notification or initiates use, they are invited to select an intervention domain(s) – hearing voices, suspiciousness, socialisation, cannabis use, perceived criticism - and then complete a series of self-assessment questions structured as question-answer exchanges that focus on cognitive appraisals, belief conviction, emotions and associated behaviours. Users can also access a menu of multi-media tools (e.g. mindfulness and relaxation exercises, educational sheets, patient recovery stories) that act in a stand-alone fashion designed to complement and support the feedback from the intervention domains.

Following a proof of concept trial (Bucci et al., 2018a), a powered Randomised Controlled Trial (RCT) was conducted to investigate the efficacy of the Actisisst app (Actissist 2.0; Bucci, 2018b). In this RCT, participants were randomly allocated on a 1:1 randomisation to receive either the Actissist app or the ClinTouch symptom monitoring app, with blind follow-up. Strategies to protect blinding included considering room use and diary arrangements and reminding participants not to disclose group allocation. ClinTouch is a symptom monitoring app (Palmier-Claus et al., 2012), with a similar look and feel and alert schedule to the Actissist app and served as an active control condition. We chose to include an active control condition in the trial to control for the non-specifics of smartphone use. ClinTouch notifications prompt users to respond to a core set of items using a touchscreen slider to rate the severity of 12 individual symptoms on a 1-7 scale, with some items seeking further detail dependent on initial rating. Symptom items have been validated against corresponding items on the Positive And Negative Syndrome Scale (PANSS; Kay et al., 1987). Unlike the Actissist app, ClinTouch does not facilitate self-initiated access; data entries must be in response to a notification.

In the current study, we explored patterns of engagement among participants who took part in the Actissist 2.0 trial over the 12-week intervention window. Specifically, using app usage data, we aimed to describe and compare patterns in the frequency, timing and duration of engagement by users across the two conditions. We also aimed to explore statistical associations between engagement, demographic and clinical characteristics and to describe the types of content with which Actissist users engaged.

2. Methods

The methods of the Actisisst 2.0 RCT pertaining to clinical outcomes are reported in the trial protocol (Bucci, 2018b); results will be published in due course. This paper focuses on the methods and results relevant to examining engagement patterns with the two apps during the trial. The trial was approved by the West of Scotland Research Ethics Committee (REC Number: 17/WS/0221). All participants gave informed consent to participate in the study procedures.

2.1. Sampling and randomisation

Participants were recruited via treating clinicians at early intervention services and community mental health teams throughout the Northwest of England between February 2018 and November 2019. Prospective participants were deemed eligible if they: met ICD-10 criteria for schizophrenia-spectrum diagnoses (specifically codes F20, F22, F23, F25, F28 or F29); were in contact with mental health services; were within five years from onset of first psychotic episode; and met a pre-determined threshold for severity of symptoms using the PANSS (Kay et al., 1987), specifically scoring over 3 (symptom present) on any PANSS positive item and any negative or general items. Individuals who were aged less than 16 years, were not proficient in English, were participating in other trials, and/or were not capable of providing informed consent were excluded.

Following recruitment, baseline assessments were completed to collect data about participant demographics and clinical characteristics. A range of validated scales were used to measure specific psychotic symptoms and other clinical characteristics: PANSS (Kay et al., 1987), Psychotic Symptoms Rating Scales (Haddock et al., 1999), Calgary Depression Scale for Schizophrenia (Addington and Addington, 1990), Personal and Social Performance Scale (Morosini et al., 2000), Perceived Criticism and Perceived Warmth Scale (Hooley and Teasdale, 1989), Questionnaire about the Process of Recovery (Neil et al., 2009), Warwick-Edinburgh Mental Wellbeing Scale (Tennant et al., 2007), Internalised Stigma of Mental Illness Inventory (Boyd et al., 2014), Empowerment Scale (Rogers et al., 1997), Alcohol Use Disorders Inventory (Babor et al., 2001), Cannabis Use Disorders Inventory-Revised (Adamson and Sellman, 2003), Alcohol, Smoking and Substance Involvement Screening Test (World Health Organization, 2002), Drug Use Disorder Identification Test-Extended (cannabis only; Berman et al., 2005), Time Line Follow Back for drugs and alcohol (Sobell and Sobell, 1992), EQ-5D-5L (EuroQolGroup, 1990) and the Client Service Receipt Inventory (Beecham and Knapp, 1992). Participants were then individually randomised at a 1:1 ratio to receive either the Actissist 2.0 app plus Treatment As Usual (TAU) or the ClinTouch app plus TAU (control arm) for 12 weeks. Participants in both groups were free to use their own personal smartphones to download their allocated app with support from a researcher or to borrow a smartphone with the app preloaded on it and data network charges covered for the intervention period.

2.2. Actissist and ClinTouch protocols

In the intervention arm of the trial, users were prompted to engage with treatment domains in the Actissist app via pseudo-random alerts, scheduled three times a day and six days a week (with a break every seventh day), between 10 am and 10 pm. Users could accept, decline or delay ('snooze' by up to a maximum of 30 minutes) prompts to interact with the app. They could also self-initiate use by accessing the app and answering questions spontaneously.

The ClinTouch app was used for participants in the control arm. In the trial, users were prompted to respond to ClinTouch symptom monitoring questions via regular alerts, scheduled to mirror the frequencies and timing of those used for the Actissist app participants. Software fixes and updates for both apps were issued during the course of the study as needed for routine maintenance (e.g. security) and in response to emergent technical issues.

At 12-week follow up assessments, which were conducted in person/over the phone, the same set of validated measures as used at baseline was repeated to measure changes in symptoms and functioning. The mobile Agnew Relationship Measure (m-ARM) was used to measure the

digital therapeutic alliance (Berry et al., 2018). The m-ARM is the mHealth version of the Agnew Relationship Measure, which is a well-validated measure of therapeutic alliance in face-to-face therapy (Agnew et al., 1998). A text message with a link to complete the m-Arm online was sent at weeks four and eight of the intervention period. As well as yielding an overall score, the m-ARM assesses five sub-components thought to contribute towards therapeutic alliance, namely bond, partnership, openness, confidence and client initiative. Bond reflects feelings of forming a bond and relationship with the DHI, partnership reflects the participant working jointly in partnership with the DHI, confidence pertains to the participant's confidence in the DHI's capacity to help; openness is characterised by the freedom of the participant to be honest and open when recording or responding to information in the DHI; and client initiative is associated with feelings of control and empowerment. App usage data linked to individual participants were wirelessly uploaded to a secure server hosted by The University of Manchester. This included responses to alerts and, for Actissist participants, engagement with particular treatment domains. Participants were reimbursed for completing baseline and follow-up assessments (£20 per session) and for travel to appointments, but not for app usage.

2.3. Data analysis

To characterise patterns of engagement we performed an unplanned, exploratory, hypothesis-generating analysis to describe and compare patterns of digital engagement among users of the Actissist and ClinTouch apps. Descriptive statistics were used to characterise engagement frequency, duration and type among each group of participants, using a range of measures described below. Analyses and visualisations were performed in R version 4.2 (R Core Team, 2022).

Among both groups, we measured engagement frequency, defined as the number of alerts completed per week (out of a maximum of 18) and overall (out of 216). Weekly engagement counts per participant were visualised using scatterplots and line graphs. Radial plots were used to visualise the timing of responses throughout the day. To measure engagement duration, we derived the time to final response for both groups of participants (in days, capped at 83). Duration of engagement for each group was visualised using Kaplan-Meier curves, with 'survival' defined as submission of any response on day 83 of the study or later. To illustrate the relationship between engagement duration and amount of data provided, we grouped participants into one of four categories, based on their time to final response: 28 days or fewer; 29 to 56 days; 57 to 82 days; and 83 days or more. Subsequently, we tested associations between engagement duration and the mean number of responses submitted weekly for the duration that participants were active.

Among Actissist users only, we also measured response types, including scheduled alerts and self-initiated responses and the overall proportion of users engaging with each treatment domain (ever; never). We also performed an analysis of the content of personal goals set by Actissist users, which were entered using free text by users on app setup. Goals were sorted into non-mutually exclusive categories (e.g. diet, physical activity and socialising) by the lead author (LH), which were then checked (by EE; differences were resolved via discussion) and frequency counts for each category were determined.

Chi squared and t-tests were used to test between group differences for binary (e.g. gender) and continuous (e.g. age) outcome data respectively. The Welch modification to the degrees of freedom was used allowing for samples with unequal variances. The log rank test was used to test the null hypothesis that there was no difference in survival between Actissist and ClinTouch participants. Anova tests were used to test associations between overall engagement frequency and categorically defined demographic characteristics (e.g. ethnicity and highest qualification). Pearson's product moment correlation was used to test associations between continuous variables (inc. age and mARM scores) and engagement outcomes. Only complete cases were used for those particular analyses affected by missing data. The P value threshold was set to 0.05.

3. Results

3.1. Sample characteristics

Of the 213 people assessed for eligibility, 172 participants were recruited and randomised to the Actissist 2.0 trial at baseline, of whom 87 were assigned to receive Actissist and 85 were assigned to receive ClinTouch. Four participants assigned to the control arm were uncontactable following randomisation, meaning 87 and 81 were onboarded onto Actissist and ClinTouch respectively.

The demographic and clinical characteristics of 168 participants who took part in the study are described in Table 1. In both arms, approximately two thirds of the sample were male (63.2 % in Actissist and 63.0 % in ClinTouch) and the mean ages were similar; specifically, 29.2 and 29.0 years for participants assigned to Actissist and ClinTouch respectively. Overall, 71.3 % of Actissist participants and 70.4 % of ClinTouch participants identified as White. Most participants – 78.2 % of Actissist and 63.0 % of ClinTouch participants- opted to borrow smartphones for the duration of the study.

Table 1
Summary sample characteristics at baseline, by condition.

	Actissist		ClinTouch	
Sample characteristics	N	%	N	%
Gender				
Female	32	36.8	30	37.0
Male	55	63.2	51	63.0
Age (mean, SD)	29.2	9.2	29.0	9.3
Ethnicity				
Arabic	1	1.2	1	1.2
Asian	13	14.9	13	16.0
Black	6	6.9	4	4.9
Mixed	5	5.8	3	3.7
White	62	71.3	57	70.4
Other	0	0	3	3.7
Highest qualification				
Primary or less	9	10.3	5	6.2
Secondary	35	40.2	40	49.4
Tertiary/further	38	43.7	32	39.5
Prefer not to say/unsure	1	1.2	0	0
Other	4	4.6	4	4.9
Employment status				
Paid or self employed	10	11.5	14	17.3
Voluntary work	1	1.2	3	3.7
Unemployed	15	17.2	10	12.3
Student	8	9.2	12	14.8
Housewife/husband	2	2.3	0	0
Exempt due to disability	40	46.0	36	44.4
Other	10	11.5	6	7.4
Relationship status				
Single	61	70.1	64	79.0
Married/civil partnership	7	8.1	7	8.6
Cohabiting	10	11.5	5	6.2
Other	9	10.3	5	6.2
Living situation				
Living alone	15	17.2	21	25.9
Living with partner	14	16.1	11	13.6
Living with parents	31	35.6	29	35.8
Living with other relatives	6	6.9	9	11.1
Living with others	8	9.2	3	3.7
Living with dependents	6	6.9	2	2.5
Would rather not say	1	1.2	2	2.5
Other	6	6.9	4	4.9
Phone and contract ownership				
Own mobile phone	83	95.4	79	97.5
Own smartphone	74	85.1	77	95.1
On pay as you go contract	38	43.7	34	42.0
Borrowed study smartphone	68	78.2	51	63.0
TOTAL	87	100	81	100

3.2. Frequency and timing of responses

Overall, Actissist participants submitted a mean of 77.1 total responses during the study compared to 60.2 responses (scheduled only) among ClinTouch participants; however, this difference was non-significant (t = 1.901, df = 163, P = 0.059). Self-initiated responses accounted for 15.4 % (N = 1,036/6,706) of all responses submitted by Actissist users. When restricted to scheduled alerts only, the mean overall response rate was 34.0 % (5,670/16,689) and 33.6 % (4,757/14,281) for participants allocated to receive Actissist and ClinTouch respectively.

Overall, 47.1 % of Actissist users (41/87) and 45.7 % of ClinTouch users (37/81) completed at least one third of all scheduled alerts issued for the period they were active in the study. Considering engagement across the whole 12-week intervention period (i.e. with the denominator set at 216 for all participants), the rates of participants who completed at least a third of all possible scheduled alerts decreased to 41.4 % of Actissist users (36/87) and 39.5 % of ClinTouch users (32/81).

Supplementary Fig. 2 illustrates the frequency of all response types (including scheduled and self-initiated alerts) each week, among individual participants for each group. Both the number of active participants (who had contributed at least one response that week) and response frequency per participant reduced over time for both groups. In the first week, the mean number of responses per participant was 12.7 and 8.9 for Actissist and ClinTouch respectively; by the final week these had dropped to 8.5 and 7.1 among active participants. As Supplementary Fig. 3 shows, the timing of responses submitted throughout the day was similar among the two groups of participants. Few responses were submitted outside of the hours of 10am-10pm for both users of Actissist (3.6 %, N = 242) and ClinTouch (1.5 %, N = 72).

Fig. 1 plots the change in cumulative probability of continued engagement in the study over time. The median survival time was 80 (CI 75-81) days for Actissist participants and 75 (CI 59-80) days for ClinTouch participants. Though the two survival curves follow a similar trajectory, the cumulative probability of retention appears to decrease less steeply over time among Actissist participants than among ClinTouch participants (Supplementary Fig. 2). Nonetheless, the log rank test showed the difference between the two groups was not significantly different (p = 0.23).

3.3. Factors associated with frequency and duration of engagement

We tested for associations between demographic characteristics and engagement frequency across the whole sample. Only age and ethnicity yielded significant associations; older age correlated positively though weakly with total responses (r = 0.210, df = 164, p = 0.003), while White ethnicity was associated with higher mean engagement frequency compared to all other non-White ethnicities (75.0 vs 53.9 total responses; t = 2.290, df = 98, p = 0.024). No significant associations were found between engagement frequency and the following (see Table 1 for categories): gender (t = 0.20, df = 122, p = 0.842); highest qualification (F(4,161) = 1.588, p = 0.18); and employment status (F(6,158) = 1.507, p = 0.179). The mean engagement frequency was significantly higher among the 29.9 % of participants who used their own smartphones for the study (87.2 vs 61.4 total responses; t = 2.612, df = 86, p = 0.011). Nonetheless, the mean engagement frequency also appeared higher among the 17 participants who did not previously own a smartphone, though not significantly so, compared to those who already owned smartphones (88.5 vs 66.8 total responses; t = 1.321, df = 18, p = 0.202).

As Fig. 2 shows, those participants who remained in the study longest also provided more data during the periods that they were active; there was a significant, moderate positive correlation between response frequency and engagement duration (r = 0.417, t = 5.876, df = 164, p < 0.001). Sensitivity analyses showed this finding was robust within both Actissist and ClinTouch subgroups.

Among the 72 (42.8 %) participants who completed the m-ARM at any time during the study, 37 were assigned to Actissist and 35 to ClinTouch. While fewer than half of participants completed the m-ARM, there were no significant differences regarding demographic characteristics – specifically, age, gender, ethnicity, highest qualification and employment status - between completers and non-completers (supplementary Table 1). Both the frequency (94.9 vs 49.3 responses; t = -5.292, df = 133, p < .001) and duration (69.2 vs 54.16 days; t = -3.690, df = 163, p < .001) of engagement were, however, significantly higher among m-ARM completers. We found a significant, moderate positive correlation between overall m-ARM scores and engagement duration among Actissist (r = 0.447, df = 35, p = 0.003), but not ClinTouch (r = 0.047, df = 33, p = 0.395) participants. Sensitivity analyses showed these findings were robust across all five m-ARM subscales

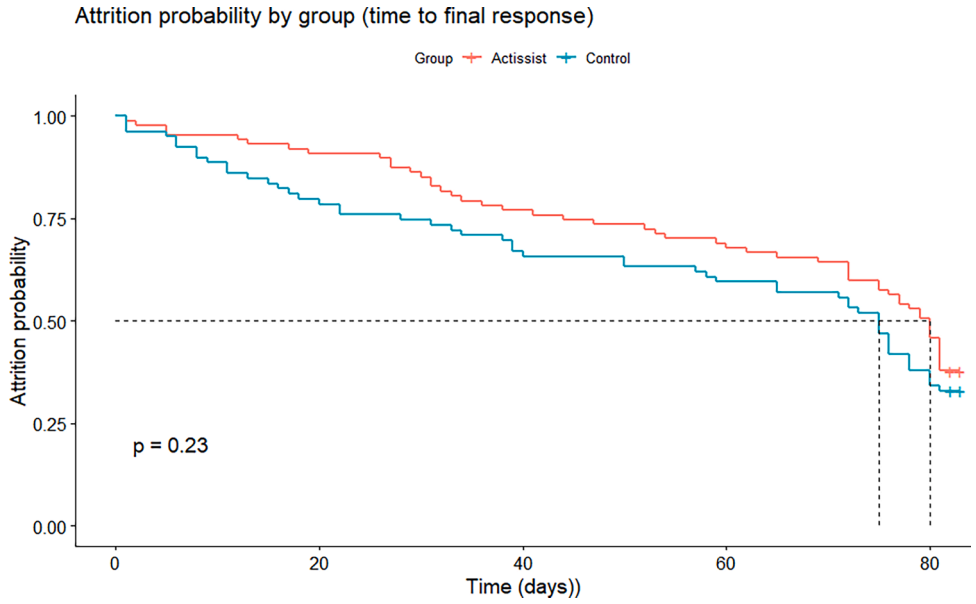

Fig. 1. (colour/online only): Participant retention over time by group (time to final data submission) with median line. *Note*: Kaplan-Meier plot indicating retention probability over time.

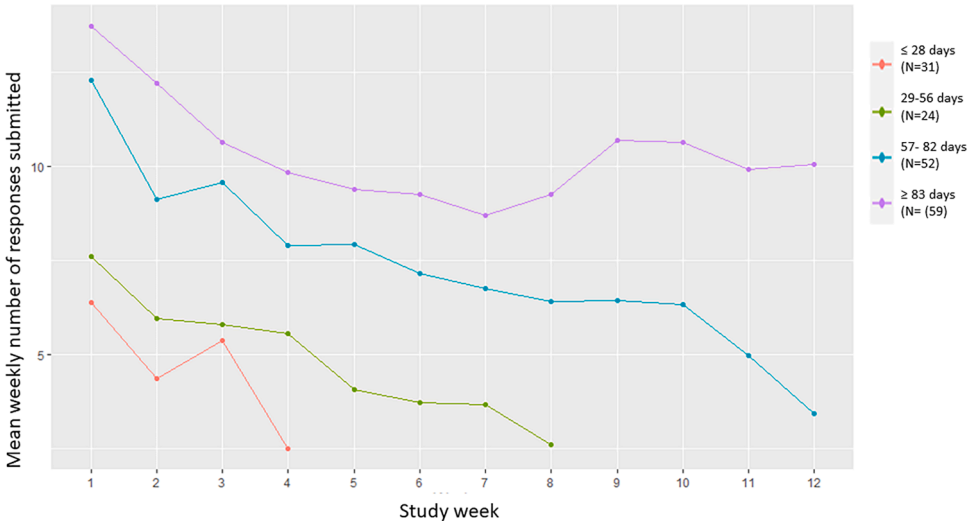

Fig. 2. (colour/online only): Mean weekly engagement over study period categorised by overall duration of participant engagement. *Note*: Coloured lines indicate groupings by overall duration of engagement (time until final response).

(supplementary Table 2).

3.4. Engagement with Actissist features

Actissist users were asked to set one to three personal goals, phrased in their own words, on app installation; 223 goals were set in total. Half of all Actissist users (53.1 %) set at least one goal related to using the Actissist app in some way (e.g. 'to use the app at least once a day'), 85 % set at least one goal unrelated to the app (e.g. 'go to the gym at least three times per week') and six (6.9 %) set none at all. The most common types of goals set involved socialising with others (48.1 %), physical activity (40.7 %) and diet and cooking (28.4 %). A breakdown of categories and example goals is provided in supplementary Table 3. There were no significant differences between people who set app-related goals and those who did not in terms of either engagement frequency ($t = 0.674$, $df = 84$, $p = 0.502$) or duration ($t = 0.714$, $df = 79$, $p = 0.477$).

Table 2 shows which of the five domains of the Actissist app users selected to work with when responding to alerts. The most frequently selected domain was voice hearing ($N = 929$) and the least accessed was cannabis ($N = 212$). The proportions of users who accessed the domains on voice hearing, criticism, socialisation and paranoia at any point during the study ranged from 80.5 % to 88.5 %. Just 40.2 % ($N = 35$) of users accessed the cannabis domain, however. Excluding the cannabis domain, 55.2 % ($N = 48$) of users accessed all four of the remaining domains at least once during the study.

Among those 35 participants who accessed the cannabis module, 15 (42.9 %) had declared cannabis use within the 3 months prior to their baseline interview. Although 'cannabis' was the domain least frequently engaged with, interactions with this domain were significantly more likely to be self-initiated than in response to scheduled alerts in comparison to other domains (46.2 % vs. 24.5 %; $x2 = 47.446$, $df = 1$, $p < .001$).

Table 2
Actissist engagement, by treatment domain.

	Number of participants selecting area at least once (%)	Number of times area selected		Response type (%)	
		Frequency	Mean (range)[1]	Scheduled	Self-initiated
Voices	70 (80.5)	929	13.3 (1-84)	697 (75.0)	232 (25.0)
Paranoia	74 (85.1)	839	11.3 (1-66)	607 (72.3)	232 (25.0)
Perceived criticism	77 (88.5)	501	6.5 (1-79)	370 (73.9)	131 (26.1)
Socialization	76 (87.4)	800	10.5 (1-75)	642 (80.2)	158 (19.8)
Cannabis	35 (40.2)	212	6.1 (1-60)	114 (53.8)	98 (46.2)

[1] Across active participants.

4. Discussion

4.1. Main findings

In both arms of this study, response rates to scheduled alerts were over 33 % and at least half of participants continued to submit responses until the final two weeks. Almost half of users completed at least a third of scheduled alerts for the period they were active in the DHI element of the study. While the frequency and duration of engagement with the intervention appeared higher among Actissist participants compared to ClinTouch participants, these differences did not reach statistical significance.

The frequency of responses per participant and number of active participants declined over time in both arms of the trial. Similar trajectories of smartphone intervention use were also observed in eight trials identified in a recent systematic review of smartphone-delivered mental health interventions (Linardon and Fuller-Tyszkiewicz, 2020).

Though the heterogeneity of interventions, engagement definitions and study designs make it difficult to directly compare studies of DHIs, levels of engagement in this study with both the Actissist and ClinTouch appeared consistent with findings of previous research studies collecting self-reported health data longitudinally (e.g. Ben-Zeev et al., 2016; Reade et al., 2017). They were, however, substantially higher than for apps generally, given a report from 2015 that the average Android app lost 77 % of daily active users within the first 3 days after the install (Chen, 2015). Indeed, only the top 50 apps (out of more than 5000) were able to retain half of daily active users for at least two weeks (Chen, 2015). It has been proposed that app engagement in research is generally elevated in comparison to real-world use (Fleming et al., 2018), likely due in part to incentives such as personalised enrollment methods and monetary compensation for continued participation (Linardon and Fuller-Tyszkiewicz, 2020). The proportion of individuals who responded to at least a third of scheduled alerts in the Actissist arm of this study was

lower than in our prior proof-of-concept trial (41 % vs 71 %); however, this is perhaps understandable given that app use in our prior study was financially incentivised (Eisner et al., 2023), unlike this RCT.

4.2. Factors influencing frequency and duration of engagement

Engagement was significantly and positively associated with therapeutic alliance, but only among Actissist participants. The question of whether and how users can build bonds with DHIs in a comparable manner to face-to-face therapy remains unanswered (Tong et al, 2022). The findings of our study suggest that a stronger sense of therapeutic alliance positively influenced engagement in this group, which makes sense given that Actissist is intended to mirror CBT with a therapist. This mirrors findings of previous studies, which have reported positive associations between increased therapeutic alliance and DHI usage (Clarke et al., 2016; Goldberg et al., 2022). Enhancing features that may improve therapeutic engagement may therefore offer one route to improving retention in future DHIs that use CBT principles.

Older age, White ethnicity and using their own smartphone were associated with higher engagement, but we found no relationship between engagement and other demographic factors. Notably, Linardon and Fuller-Tyszkiewicz's review (2020) reported no reliably consistent associations between participant-level characteristics and adherence/attrition in studies of mental health DHIs. While associations between individual characteristics and engagement - including older age and White ethnicity – have also been reported by a handful of previous studies (e.g. Eisner et al., 2023; Ben-Zeev et al., 2016), the reasons for these patterns are unclear. Such findings may warrant further attention, for this and other DHIs, if engagement is to be optimised for a diverse group.

The ability to self-initiate responses and to access interventions on a '24/7' basis is frequently touted as a theoretical benefit of using DHIs over in-person services. Nonetheless, we found that engagement with Actissist occurred predominantly around the timing of prompts, though both modes were well used. This is consistent with other DHI studies of people with psychosis, which have reported that participants respond to prompts or notifications more than they self-initiate assessments (Ben-Zeev et al., 2016). People who used the cannabis module – over half of whom did not report recent cannabis use at baseline - were more likely to self-initiate use, however, suggesting that self-initiated use may be advantageous for particular problem areas. Whilst the level of engagement for both apps in the Actissist2 trial is substantial when compared to the average Android app, attrition related to continued app use remains problematic for the field. Two key factors that show promise in improving engagement with DHIs include integrating human feedback and support with a DHI Torous Lipschitz et al. (2021), involving the end user in the design of the DHI and study procedures, ideally using participatory design methods (Bucci et al., 2019).

4.3. Strengths and limitations

This study exploited the objective and detailed usage data from two DHIs, combined with demographic data, to characterise engagement over time and explore factors affecting both engagement frequency and duration. Nonetheless, we did not define *a priori* hypotheses or predetermined engagement thresholds, thus this was an exploratory analysis and relationships cannot necessarily be interpreted in causal terms and certain analyses may not be sufficiently powered.

Our sample was well-balanced in terms of gender, ethnicity and other demographic factors; however, it is plausible that the trial attracted more digitally literate individuals, with more positive attitudes towards DHIs than the broader population of people with psychosis. During the first four months of the study, technical issues meant the audible tone among some of the handsets loaned to participants were muted; however, this was fixed and on investigation there was no evidence to suggest participants in the two arms were unequally affected.

While certain aspects of this RCT were designed to more realistically reflect real-world conditions (e.g. lack of financial incentives for app usage), others (e.g. provision of phones and data plans) may limit generalisability. The measures administered in the Actissist2 randomised controlled trial, though not factored into the analyses reported here, might have influenced both engagement and alliance with the apps.

Furthermore, some of our analyses, particularly those examining therapeutic alliance, suffered from missing data. While there were no significant demographic differences between responders and non-responders, this - and the other factors discussed- do warrant some level of caution in our interpretation.

5. Conclusions

Achieving satisfactory engagement in the context of DHIs is a major challenge and, arguably, a pre-requisite for effecting health improvements. This study has exploited usage data from two DHIs designed for people with psychosis to provide a detailed analysis of patterns of engagement and attrition. We have demonstrated that the trial retained a substantial proportion of participants for the duration of the study in both arms of the trial, while striving for realistic recruitment and retention strategies for use in real-world situations. Furthermore, older age, White ethnicity, using their own smartphone device and, among Actissist users, an increased sense of therapeutic alliance were identified as predictors of increased engagement. Future studies should explore the relevance of therapeutic alliance and take advantage of opportunities to exploit detailed usage data to inform the real-world implementation of DHIs with diverse samples in practice.

Author Statement

LH conducted the analysis and wrote the first draft of the paper. LH, EE and SB were involved in interpreting the analysis. SB, RE, KB, JA, SL, GH and DE designed the Actissist2 trial. All authors contributed to the article, reviewed the paper, and approved the submitted version.

Declaration of Competing Interest

Bucci, Ainsworth and Lewis are Directors and shareholders of CareLoop Health Ltd, which develops and markets digital therapeutics for schizophrenia and a digital screening app for postnatal depression. All other authors declare no conflicts of interest.

Acknowledgements

The authors thank the service users, clinical teams, and our patient and public involvement contributors for supporting the study. Thank you to the research staff for their work.

The work was supported by the Medical Research Council Developmental Pathway Funding Scheme (grant number MR/P026664/1) and was supported by the University of Manchester, Greater Manchester Mental Health NHS Foundation Trust, Pennine Care NHS Foundation Trust and the Clinical Research Network.

Bucci is supported by a National Institute for Health Research (NIHR) Research Professorship. Bucci also reports research funding from the Wellcome Trust.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.psychres.2023.115536.

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