The Horyzons project: a randomized controlled trial of a novel online social therapy to maintain treatment effects from specialist first-episode psychosis services

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This study aimed to determine whether, following two years of specialized support for first-episode psychosis, the addition of a new digital intervention (Horyzons) to treatment as usual (TAU) for 18 months was more effective than 18 months of TAU alone. We conducted a single-blind randomized controlled trial. Participants were people with first-episode psychosis (N=170), aged 16-27 years, in clinical remission and nearing discharge from a specialized service. They were randomly assigned (1:1) to receive Horyzons plus TAU (N=86) or TAU alone (N=84) between October 2013 and January 2017. Horyzons is a novel, comprehensive digital platform merging: peer-to-peer social networking; theory-driven and evidence-informed therapeutic interventions targeting social functioning, vocational recovery and relapse prevention; expert clinician and vocational support; and peer support and moderation. TAU involved transfer to primary or tertiary community mental health services. The primary outcome was social functioning at 18 months as measured by the Personal and Social Performance Scale (PSP). Forty-seven participants (55.5%) in the Horyzons plus TAU group logged on for at least 6 months, and 40 (47.0%) for at least 9 months. Social functioning remained high and stable in both groups from baseline to 18-month follow-up, with no evidence of significant between-group differences (PSP mean difference: –0.29, 95% CI: –4.20 to 3.63, p=0.77). Participants in the Horyzons group had a 5.5 times greater increase in their odds to find employment or enroll in education compared with those in TAU (odds ratio, OR=5.55, 95% CI: 1.09-28.23, p=0.04), with evidence of a dose-response effect. Moreover, participants in TAU were twice as likely to visit emergency services compared to those in the Horyzons group (39% vs. 19%; OR=0.31, 95% CI: 0.11-0.86, p=0.03, number needed to treat, NNT=5). There was a non-significant trend for lower hospitalizations due to psychosis in the Horyzons group vs. TAU (13% vs. 27%; OR=0.36, 95% CI: 0.11-1.08, p=0.07, NNT=7). So, although we did not find a significant effect of Horyzons on social functioning compared with TAU, the intervention was effective in improving vocational or educational attainment, a core component of social recovery, and in reducing usage of hospital emergency services, a key aim of specialized first-episode psychosis services. Horyzons holds significant promise as an engaging and sustainable intervention to provide effective vocational and relapse prevention support for young people with first-episode psychosis beyond specialist services.

Key words: Horyzons, first-episode psychosis, digital intervention, peer support, social functioning, employment, educational attainment, use of emergency services, hospitalization

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Psychosis can be a devastating mental health condition. It typically emerges in adolescence or early adulthood, significantly disrupting achievement of educational, occupational and social milestones and, in many cases, follows a relapsing course, leading to long-term disability[1]. Early intervention – in the form of youth-specific, recovery-focused specialized first-episode psychosis (FEP) services – is now widely seen as the most evidence-based approach to improving the long-term outcomes of psychosis[2].

There are, however, several limitations to the impact of early intervention services. First, specialist FEP services typically provide intensive support for two years, and two clinical trials indicated that some treatment benefits seen at the end of this period may not persist over time[3,4]. Second, social, educational and vocational recovery typically lags behind symptomatic remission, and many young people experience enduring social functioning deficits, and low educational completion and high unemployment rates[5]. Finally, the risk for relapse and hospital admissions remains high beyond discharge from specialized FEP services[1,3,4].

The recognition of these limitations has created an impetus for improving long-term recovery from early psychosis. Along with studies evaluating psychosocial interventions focused on preventing relapse[6] and fostering social and vocational recovery[5,7], three recent clinical trials have evaluated the effects of extending the duration of specialist support (by one[8] to three[9,10] years) compared with the typical timeframe of early intervention services (i.e., two years). These trials have yielded mixed findings, with one of them showing improved length of remission of positive and negative symptoms in the extended model of care (five years) relative to regular care[10], one failing to demonstrate additional benefits from extended specialist support[9], and one showing improved functional outcomes after three years of specialized care which were not sustained at one and two years post-specialist intervention[8].

A promising and potentially cost-effective alternative to extending the duration of specialist FEP services is to provide lower intensity, maintenance treatment following the initial two years

of specialist support[11]. Online, mobile and social media-based interventions provide a novel avenue to offer young people lower intensity, effective, sustainable and scalable support beyond discharge from specialist FEP services. Indeed, preliminary research indicates that online and mobile-based interventions are feasible, acceptable and may improve a range of important domains in early psychosis, including negative symptoms, psychotic symptoms, depression, social functioning, subjective well-being and loneliness[12,13]. Furthermore, initial evidence shows that young people with mental ill-health find online social media-based interventions easy to use, engaging and supportive[14].

Recent psychological models have proposed self-efficacy[15], intrinsic motivation and positive emotions[16] as important targets to promote social functioning in psychosis. Strengths- and mindfulness-based interventions have been put forward as key approaches to increase self-efficacy and positive emotions[17], respectively, with preliminary studies supporting their potential to improve social functioning in psychosis[18]. Similarly, self-determination theory posits that interventions addressing the basic psychological needs of competence, autonomy and relatedness will increase engagement and improve overall functioning through enhanced intrinsic motivation[19]. Recent studies support this theory by showing that increases in intrinsic motivation predict improvements of social functioning in FEP[20].

Drawing on our previous evidence-based interventions in preventing psychosis relapse[6] and improving vocational attainment[5] in FEP, combined with novel approaches to social recovery (strengths- and mindfulness-based interventions) and the principles of self-determination theory, our team developed a world-first digital intervention (Horyzons) designed to foster long-term recovery in FEP. Horyzons blends evidence-based models of social functioning, vocational recovery and relapse prevention into a therapeutic social media environment supported by peer workers as well as clinicians and vocational professionals.

The aim of this study was to examine, via a single-blind randomized controlled trial, whether extending the treatment period of a specialist FEP service through this novel digital intervention added to treatment as usual (TAU) for 18 months was more effective in improving social functioning (primary outcome variable) compared to TAU alone. Among secondary outcomes, we explored the impact of Horyzons plus TAU compared to TAU alone on vocational/educational recovery, visits to emergency services, and hospitalizations due to psychosis during the 18-month follow-up period.

METHODS

Design and participants

The Horyzons study was an 18-month, parallel-group, single-blind, phase 4 randomized controlled trial. Participants were aged 16-27 years and were receiving care at the Early Psychosis Prevention and Intervention Centre (EPPIC), a specialized program of Orygen, Melbourne (Australia). EPPIC is a publicly-funded program servicing 250-300 new FEP referrals per year. It provides 18-24 months of specialized care, after which patients are discharged and transferred to TAU[21].

The study protocol was registered (ANZCTR; ACTRN1261 4000009617) and has been described in detail elsewhere[22]. The trial was approved by the Melbourne Health Human Research Ethics Committee (HREC/12/MH/151; ref. 2013.146).

Inclusion criteria for participants were: a) a first episode of a DSM-IV psychotic disorder or mood disorder with psychotic features; b) aged 16-27 years; c) remission of positive symptoms of psychosis – defined, using the Positive and Negative Syndrome Scale (PANSS)[23], as four weeks or more of scores of 3 (mild) or below on items P2 (conceptual disorganization) and G9 (unusual thought content), and scores of 4 (moderate) or below with no functional impairment on items P3 (hallucinatory behaviour) and P1 (delusions).

Additional inclusion criteria to ensure low level of risk within the trial included: d) low aggressiveness, defined by a score of 3 or below on the poor impulse control item of the PANSS for the month prior to study entry; and e) moderate or lower suicidal risk, defined as a score of 4 or below on the suicidality subscale of the Brief Psychiatric Rating Scale (BPRS)[24] for the month preceding study entry. Finally, participants were required to nominate an emergency contact to be eligible for the study.

Exclusion criteria were: a) intellectual disability; and b) inability to converse in or read English. Additional exclusion criteria to ensure safety within the trial were: c) a DSM-IV diagnosis of either antisocial personality disorder (ASPD) or borderline personality disorder (BPD), as well as clinical evidence that BPD features caused interpersonal difficulties in the treatment environment.

The Structured Clinical Interview for DSM-IV-TR Axis I Disorders, Research Version, Patient Edition (SCID-I/P)[25] was used as the standardized measure of DSM-IV diagnosis of mental illness. The BPD (13 items) and Conduct Disorder/ASPD (22 items) screening questions of the Structured Clinical Interview for DSM-IV Axis II Personality Disorders (SCID-II) were used to assess for BPD and ASPD[26].

All participants provided written informed consent, which was also obtained from a parent or legal guardian if the participant was younger than 18 years. Recruitment occurred between October 2013 and January 2017. Participants completed four assessments with research assistants at baseline, and at months 6, 12 and 18.

Randomization and patient allocation

Participants were randomly assigned (1:1), following discharge from two years of specialized treatment, to either TAU plus Horyzons or TAU alone for 18 months. An external independent statistician created a computer-generated randomization schedule, comprising randomly permuted blocks. To ensure allocation concealment, the trial coordinator was notified of each randomization via a secure online system and then informed participants of their treatment allocation.

Statisticians and study assessors were masked to treatment allocation until completion of analyses via various procedures detailed in the study protocol[22]. If a study assessor was unblinded, the corresponding participant was allocated to a different study assessor. The study assessors recorded their best guess of participants' treatment allocation at 6-, 12- and 18-month follow-up to assess the success of masking.

Experimental intervention

The Horyzons application was iteratively developed by a multidisciplinary team, in partnership with young people, with the aim of improving social functioning and vocational recovery and prevent relapse in FEP[22].

Horyzons is based on the moderated online social therapy (MOST) model[27,28], which integrates interactive online therapy ("pathways" and "steps"), peer-to-peer online social networking ("the café"), peer moderation, and expert support. Details on each of these components are given in Table 1.

Expert support was provided by registered mental health clinicians (e.g., clinical psychologists, social workers) and vocational workers (trained in Individual Placement and Support) with experience in young people with psychosis. The role of clinicians was to tailor evidence-based interventions, monitor participants' clinical status and ensure the safety of the social network. Each clinician was assigned a caseload, which was followed for the duration of the trial. After baseline assessment, the clinician contacted the participant for a brief phone meeting to review personal needs and preferences. During this initial call, the clinician collaboratively agreed with the participant on the expectations regarding frequency of logins (i.e., weekly or fortnightly). Clinicians then developed brief case formulations which were discussed during weekly supervision meetings with senior clinical psychologists from the team. Guided by the individual formulation, clinicians sent each client weekly tailored content suggestions.

The activity of moderators was informed by the self-determination theory. They supported the autonomy, self-competence and relatedness needs of participants when using Horyzons. For those young people requiring vocational assistance, the vocational moderator provided them with individualized online support, which included: assessing preferences for training, identifying suitable job openings, supporting specific job seeking activities, preparing for a job interview, support for work and study demands, and encouraging use of their personal strengths. Vocational support and online content were informed by the Individual Placement and Support model[5].

The "café" was led by trained young people with lived experience of mental illness ("peer-workers"). They facilitated social learning using Horyzons in desired ways (e.g., sharing helpful

Table 1 Description of Horyzons features

Therapy content	
Pathways	Horyzons includes a number of online "pathways" addressing distinct themes, such as understanding psychosis, identifying early warning signs and preventing relapse, fostering vocational skills, identifying and exercising personal strengths, promoting positive connections with others, fostering positive emotions, managing anxiety and dealing with depression.
Steps	To increase the usability and take-up of therapeutic content, pathways are comprised of thematically related therapy "steps". The online "steps" are evidence-based, discrete, interactive therapy modules primarily targeting: a) social functioning; for example, through fostering self-efficacy (e.g., by identifying personal strengths via an interactive card-sort game based on the strengths-based framework) and positive connections with others (e.g., by illustrating positive and negative responses and relationship dynamics with others); b) vocational recovery; for example, by providing interactive information on how to prepare for a job interview, or how to use personal strengths at work and study; c) relapse prevention; for example, by identifying early warning signs of relapse and developing a relapse prevention plan; and d) comorbid anxiety and depression symptoms; for example, by engaging in relaxation, mindfulness or behavioural activation.
Online social network (Café)	To enhance engagement and foster social support, participants are encouraged to communicate with one another through the online social network. Expert moderators (clinicians and vocational workers) are identifiable as a separate user class within the network. Posts include "icebreakers" (to encourage social interactions), user-generated threads, "reactions" (designed to facilitate social support), as well as content related to mental health or of general interest.
Step content	
Key concepts	Accessible psychoeducational descriptions of therapeutic concepts and outlines based on the purpose of the particular step for the participants.
Comics	Therapy comics, each comprising of 20 to 24 story board panels focusing on a particular therapeutic theme and target related to the treatment.
Do its	To ensure that therapeutic concepts are translated into behavioural change, the "steps" include behavioural prompts known as actions or "Do its". For example, following a step about finding jobs, the participants would find specific behavioural suggestions prompting them to "drop off their CV in the reception areas of 10 different organizations". "Do its" are also related to the participant's specific strengths (e.g., using courage when facing stressful social situations).
Talk it out	"Talk it out" is an online group function informed by the evidence-based problem-solving framework. It enables participants to propose problems (e.g., "should I discuss my mental health issues in a job interview?"), which are discussed in moderated groups through structured phases (e.g., brainstorming, pros and cons, wrap-up). Previous problems and group solutions are stored in the system, providing an easily accessible "solution wiki" for future young people.

content). Peer-workers also seeded discussion threads to promote engagement and connection and to normalize experiences.

Control intervention

Participants allocated to regular care received TAU following discharge from the EPPIC program. We chose TAU as comparator to enhance external validity because it replicates the current mainstream post-discharge treatment options available to young people with FEP. This parallels three recent randomized controlled trials examining extended interventions for FEP services[8-10].

TAU comprised various treatment options delivered by generic medical or mental health services typically available to young people. Those with complex needs were referred by the EPPIC team to adult tertiary community mental health services, whereas those who achieved a good level of recovery and clinical stability were referred to primary care services (including access to multidisciplinary youth mental health services and government-subsidized psychological and psychiatric treatment). TAU participants were also provided with a printed leaflet and a universal serial bus (USB) containing relevant information on free online youth resources (i.e., Moodgym, e-headspace, Reach-out).

Outcome measures

The primary outcome was change in social functioning, as measured by the Personal and Social Performance Scale (PSP)[29], from baseline to 18-month follow-up. Secondary outcomes (change from baseline to 18-month follow-up, or incidence within the 18-month follow-up) included visits to emergency services, hospital admissions due to mental health issues in general or specifically to psychosis, vocational/educational recovery (i.e., working in a job that paid the legislated minimum wage for a minimum of a week and/or being enrolled in education in the previous 6-month period), depression (as assessed by the Calgary Depression Scale for Schizophrenia, CDSS[30]), loneliness and social support (evaluated by the UCLA Loneliness Scale, Version 3[31], and the Medical Outcomes Study Social Support Survey, MOS-SSS[32], respectively), self-esteem and self-efficacy (assessed by the Self-Esteem Rating Scale - Short Form, SERS-SF[33], and the Mental Health Confidence Scale, MHCS[34], respectively), satisfaction with life (evaluated using the Satisfaction with Life Scale, SWLS[35]), quality of life (measured by the Assessment of Quality of Life - 8D, AQoL-8D[36]), and positive and negative psychotic symptoms (assessed by the PANSS).

Seventeen cases were selected at baseline for the purpose of checking interrater reliability on the interview rated measures – PSP, PANSS and CDSS – with an independent research assistant making simultaneous ratings. The intraclass correlation coefficients were 0.90 for PSP, 0.89 for PANSS, and 0.94 for CDSS, which indicates good interrater reliability.

To determine success of blinding, the kappa statistic was used as a measure of agreement beyond that caused by chance[37]. The guesses by the study assessors about treatment group were compared with actual treatment allocation. There was no evidence of unblinding by study assessors. The kappa statistics were 0.01, 0.08 and 0.29 at 6-, 12- and 18-month follow-up assessments, respectively. A kappa statistic of less than 0.40 indicates poor agreement[37].

Data analysis

The main analyses were done on an intention-to-treat basis, including all participants and all available data. Additional analyses were completed on *a priori* established per-protocol basis, including participants in the intervention group who received a pre-specified minimal exposure to the online intervention (i.e., >8 logins during the 18-month intervention[22]).

For continuous variables, we compared the groups using linear mixed models with a restricted maximum likelihood estimator implemented by the lme4 (version 1.1-23) and lmerTest (version 3.1.2) packages in R (version 3.6.2). The models included random intercepts for each participant, and the fixed effects of treatment, time (baseline, 6-, 12- and 18-month follow-up), and treatment-by-time interactions. Gender, age, the relevant baseline scores of the outcome variable, and covariates which were significantly different across treatment groups at baseline (i.e., duration of untreated psychosis, DUP) were also included as fixed effects (i.e., controlling for their effects).

Vocational/educational outcome (categorical) was analyzed using multilevel logistic regression including random intercepts for each participant, and the fixed effects of treatment, time, treatment-by-time interactions, gender, age and other relevant covariates as described above.

For all analyses, the primary effects of interest were the treatment-by-time interactions representing group differences in linear change from baseline to month 18 (primary end point).

The total number of hospital admissions due to psychosis or in general to mental health issues and of visits to emergency services over the 18-month follow-up period were compared between groups using logistic regression, including gender, age and DUP as covariates in the models. We used two-tailed tests with $p<0.05$ denoting statistical significance.

In addition to the planned contrast of interest for changes between baseline and 18 months, we also examined group differences at 6 and 12 months if there was a statistically significant overall treatment-by-time interaction.

RESULTS

Eighty-six participants (50.5%) were randomly assigned to the Horyzons plus TAU group and 84 (49.5%) to the TAU group. Participants had a mean age of 20.91 years (SD=2.88) (Table 2). With the exception of DUP, which was significantly longer in the Horyzons plus TAU group (median: 7.36 weeks) relative to the TAU group (median: 4.29 weeks), all socio-demographic and diagnostic covariates were

Table 2 Baseline patient characteristics

	Horyzons plus TAU (N=86)	TAU (N=84)	Total (N=170)
Age (years, mean±SD)	21.01±2.93	20.81±2.83	20.91±2.88
≤18 years, N (%)	23 (26.7)	25 (29.8)	48 (28.2)
>18 years, N (%)	63 (73.3)	59 (70.2)	122 (71.8)
Gender, N (%)			
Males	45 (52.3)	45 (53.6)	90 (52.9)
Females	41 (47.7)	39 (46.6)	80 (47.1)
Employment status, N (%)			
Unemployed	32 (39.0)	24 (29.3)	56 (34.1)
Studying only	16 (19.5)	23 (28.0)	39 (23.8)
Paid work only	20 (24.4)	17 (20.7)	37 (22.6)
Concurrent study and paid work	14 (17.1)	18 (22.0)	32 (19.5)
Educational status, N (%)			
Not currently studying	54 (62.8)	39 (46.4)	93 (54.7)
Not currently studying, but enrolled in upcoming course	2 (2.3)	4 (4.8)	6 (3.5)
Studying part-time	5 (5.8)	14 (16.7)	19 (11.2)
Studying full-time	25 (29.1)	27 (32.1)	52 (30.6)
Highest year completed at school, N (%)			
Year 8	1 (1.2)	2 (2.4)	3 (1.8)
Year 9	7 (8.2)	7 (8.3)	14 (8.3)
Year 10	16 (18.8)	19 (22.6)	35 (20.7)
Year 11	16 (18.8)	20 (23.8)	36 (21.3)
Year 12	45 (52.9)	36 (42.9)	81 (47.9)
Diagnosis, N (%)			
Affective psychosis	29 (33.7)	29 (34.5)	58 (34.1)
Non-affective psychosis	57 (66.3)	55 (65.5)	112 (65.9)
Duration of untreated psychosis (weeks, median and range)*	7.36 (1.00-52.14)	4.29 (0.64-11.93)	4.29 (0.86-19.57)

TAU – treatment as usual
*Significant difference between TAU and Horyzons plus TAU ($p<0.05$)

well balanced between groups at baseline (Table 2). There were no differences between participants who were included in the study and those who declined participation in terms of age and gender.

Seventy-two of 86 participants in the Horyzons plus TAU group (83.7%) and 75 of 84 in the TAU group (89.3%) completed at least one post-baseline (i.e., 6-, 12- and/or 18-month) assessment. Moreover, 63 participants in the Horyzons group (73.2%) and 63 in the TAU group (75.0%) completed the 18-month follow-up assessment (see Figure 1). There were no differences between those who were lost to follow-up and those who completed the 18-month assessment with respect to socio-demographic, diagnostic, clinical and functioning variables.

Data on engagement with Horyzons are provided in Table 3. Participants had an average of 106.84 logins (SD=247.05), with 69 (80.2%) participants logging on for at least 3 months, 47 (55.5%) for at least 6 months, 40 (47.0%) for at least 9 months, and 25 (29.0%) for at least 12 months.

For our primary outcome variable, changes in PSP scores at 18-month follow-up, we found no significant group-by-time interaction effect (mean difference = –0.29, 95% CI: –4.20 to 3.63, standardized effect size = –0.01, p=0.77) in the main intention-to-treat analysis. Level of functioning remained stable for both groups from baseline to 18-month follow-up (Table 4).

We found a significantly better vocational/educational outcome in the Horyzons plus TAU group compared with the TAU group (Table 5). Specifically, participants in the Horyzons group had 5.5 times greater increase in their odds of finding employment or enrolling in education from baseline to 18 months compared with those in the TAU group (odds ratio, OR=5.55, 95% CI: 1.09-28.23, p=0.04). Moreover, participants allocated to the TAU group had twice the rate of hospital admissions due to psychosis compared with their counterparts in the Horyzons plus TAU group, although this difference did not reach the level of statistical significance (27% vs. 13%, respectively; OR=0.36,

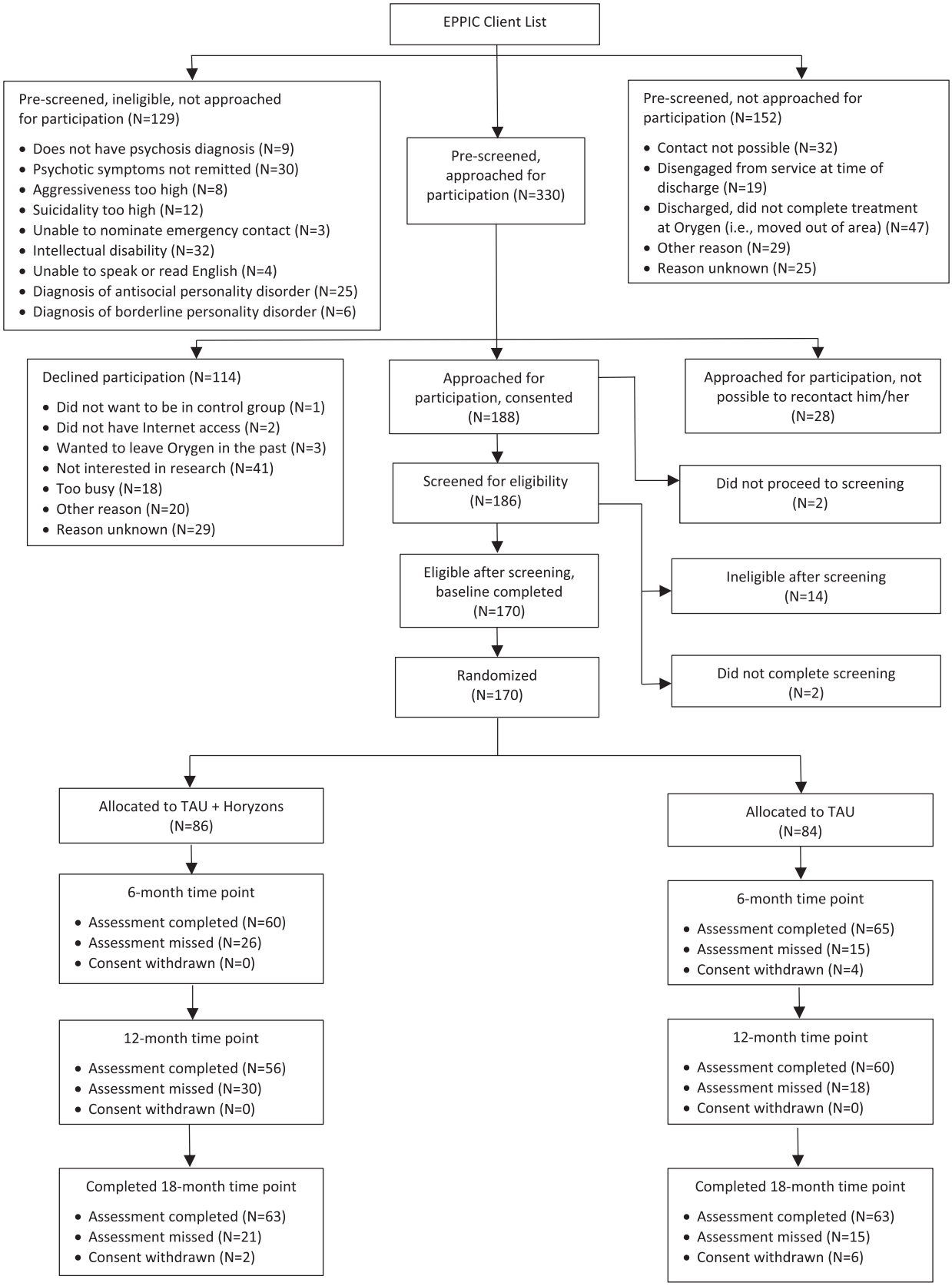

Figure 1 Trial profile. EPPIC – Early Psychosis Prevention and Intervention Centre, TAU – treatment as usual

Table 3 Engagement with Horyzons

	N (%)	Mean (SD)	Median (IQR)
Number of logins over 18 months		106.84 (247.05)	24 (8.5-84)
≤8	21 (24.7)		
9-17	15 (17.6)		
18-76	24 (28.2)		
77-1,529	25 (29.4)		
Number of steps done		16.99 (21.76)	9 (3-21)
1-5	30 (35.3)		
6-15	26 (30.6)		
16-130	29 (34.1)		
Number of actions done		5.29 (8.11)	2 (0-7)
None	27 (31.8)		
1-5	32 (37.6)		
6-47	26 (30.6)		
Number of newsfeed posts and/or comments		21.49 (41.71)	7 (1.25-21)
None	14 (16.7)		
1-5	25 (29.8)		
6-25	29 (34.5)		
26-266	16 (19.0)		
Length of engagement (months)		8.15 (5.65)	7 (3-13)
At least 1 month	76 (88.4)		
At least 3 months	69 (80.2)		
At least 6 months	47 (55.5)		
At least 9 months	40 (47.0)		
At least 12 months	25 (29.0)		
Full 18-month period	7 (8.1)		

IQR – interquartile range

95% CI: 0.11-1.08, p=0.07, number needed to treat, NNT=7) (Table 5). Consistent with this finding, those allocated to the TAU group had twice the rate of visits to emergency services compared with those in the Horyzons plus TAU group from baseline to 18 months, a statistically significant difference (39% vs. 19%, respectively; OR=0.31, 95% CI: 0.11-0.86, p=0.03, NNT=5) (Table 5).

Changes in other secondary outcome variables did not differ between the groups from baseline to 18-month follow-up (Table 4). Additional analyses to the primary contrast of interest (changes between baseline and 18 months) found a significant overall treatment-by-time interaction effect on negative symptoms (as measured by the PANSS scale). Post-hoc analyses revealed that this effect was driven by a significantly greater reduction of negative symptoms in participants allocated to the Horyzons plus TAU compared with those in the TAU group from baseline to 12-month follow-up (p<0.05); however, these effects on negative symptoms were lost from 12-month to 18-month follow-up.

Effect sizes from the per-protocol analyses were consistent with the primary intent-to-treat analyses.

DISCUSSION

Sustained social and vocational recovery is the ultimate goal of specialist FEP services as well as the most valued outcome by young people and their families[38]. Yet, follow-up studies have questioned the maintenance of treatment effects of early psychosis services[3,4]; social and vocational recovery continues to be resistant to current intervention approaches[5]; and relapse rates remain high beyond discharge from specialized services[1,3,4]. Addressing this gap, this is the first randomized controlled trial to examine whether a novel digital intervention is an effective strategy to extend the treatment benefits of early intervention and foster social and vocational recovery beyond discharge from specialist FEP services.

We did not find a significant between-group difference in social functioning (primary outcome) as measured by the PSP at 18 months. Participants in both groups showed relatively high levels of social functioning at baseline, which were maintained throughout the study. On the other hand, secondary analyses revealed that participants who received the Horyzons intervention plus TAU had a 5.5 times greater increase in their odds of finding competitive employment and/or enroll in education – a key aspect of functional recovery – compared with those receiving TAU alone from baseline to 18 months. Moreover, we found twice the incidence of hospital admissions due to psychosis in the TAU group than in the Horyzons plus TAU group. While the between-group difference did not reach the level of statistical significance (p=0.07) (event rates were low), the differential rate is notable, and this suggestive evidence is supported by the consistent finding that participants allocated to the Horyzons intervention were significantly less likely to visit emergency services over the 18-month period (p=0.03) compared with their counterparts in the TAU group.

In line with previous studies, we hypothesized that the potentially disruptive effects of transfer of care from a specialized to generic services, coupled with the sense of loss, change of clinical care and reduced multidisciplinary input would lead to a functional deterioration in the TAU group[3]. This would have been consistent with Chang et al's finding that the functional decline following termination of specialized care took place primarily in the first year following discharge[8]. By contrast, in keeping with previous research[11], we expected that, by providing an online step-down model of care, we would prevent the loss of functional gains in the Horyzons group. Contrary to our expectations, while participants allocated to the Horyzons plus TAU group maintained their level of functioning throughout the study, so did those in the TAU group.

There are a number of explanations that could account for this finding. First, baseline social functioning in our sample (at the point of discharge from a specialist FEP service) was noticeably

Table 4 Social functioning and continuous secondary outcome variables at baseline and 18 months (intent-to-treat analysis)

	Horyzons plus TAU	TAU	Mean difference (95% CI)	Standardized effect size	p
Social functioning (PSP score, mean±SE)			–0.29 (–4.20 to 3.63)	–0.01	0.77
Baseline	67.36±1.21	66.37±1.24			
18 months	67.04±1.38	66.75±1.42			
Depression (CDSS score, mean±SE)			0.31 (–0.82 to 1.44)	0.05	0.42
Baseline	3.23±0.35	3.00±0.36			
18 months	4.13±0.40	4.44±0.41			
Loneliness (UCLA score, mean±SE)			0.94 (–2.05 to 3.94)	0.06	0.54
Baseline	46.06±0.89	46.12±0.94			
18 months	44.12±1.05	45.07±1.10			
Social support (MOS-SSS score, mean±SE)			0.08 (–5.51 to 5.68)	–0.003	0.82
Baseline	71.11±1.68	70.45±1.75			
18 months	72.99±1.96	73.08±2.05			
Self-esteem (SERS-SF score, mean±SE)			1.07 (–4.89 to 7.04)	0.03	0.89
Baseline	12.24±1.79	12.84±1.88			
18 months	13.78±2.09	14.85±2.19			
Self-efficacy (MHCS score, mean±SE)			2.25 (–2.14 to 6.65)	0.09	0.30
Baseline	68.22±1.31	67.84±1.35			
18 months	68.57±1.56	70.82±1.59			
Satisfaction with life (SWLS score, mean±SE)			–0.29 (–2.13 to 1.55)	–0.03	0.67
Baseline	20.99±0.56	21.19±0.59			
18 months	22.63±0.65	22.34±0.67			
Quality of life (AQoL-8D total score, mean±SE)			0.01 (–0.04 to 0.07)	0.05	0.59
Baseline	0.60±0.02	0.60±0.01			
18 months	0.63±0.02	0.65±0.02			
Positive symptoms (PANSS Positive score, mean±SE)			–0.82 (–1.98 to 0.35)	–0.12	0.37
Baseline	10.02±0.36	9.68±0.37			
18 months	11.08±0.41	10.26±0.43			
Negative symptoms (PANSS Negative score, mean±SE)			–0.83 (–1.99 to 0.34)	–0.12	0.34
Baseline	11.21±0.36	11.05±0.37			
18 months	12.26±0.41	11.43±0.42			

The p value represents the group-by-time interaction effect from baseline to 18-month follow-up. TAU – treatment as usual, PSP – Personal and Social Performance Scale, CDSS – Calgary Depression Scale for Schizophrenia, UCLA – UCLA Loneliness Scale (Version 3), MOS-SSS – Medical Outcomes Study Social Support Survey, SERS-SF – Self-Esteem Rating Scale - Short Form, MHCS – Mental Health Confidence Scale, SWLS – Satisfaction with Life Scale, AQoL-8D – Assessment of Quality of Life - 8D, PANSS – Positive and Negative Syndrome Scale

higher compared to other similar studies. Specifically, the mean social functioning score at study entry was 66.6 in our trial (PSP), compared with 57 (Social and Occupational Functioning Assessment Scale, SOFAS) in Chang et al's study[8] and 48 (PSP) in Albert et al's trial[9]. Moreover, DUP – a marker of both long-term functioning and treatment response in extended specialist FEP services[39,40] – was also comparatively briefer in our cohort (4.3 weeks) vs. prior studies (121-164 weeks in Albert et al's study[9], 12 weeks in Malla et al's study[10], 13 weeks in Chang et al's trial[8]). These differences could reflect the intensity and quality of the background treatment in our study. In particular, unlike other specialized FEP services, EPPIC provides a comprehensive group program and Individual Placement and Support to promote social and vocational recovery as part of the service. Alternatively, the inclusion

Table 5 Binary secondary outcome variables (intent-to-treat analysis)

	Horyzons plus TAU, N (%)	TAU, N (%)	Odds ratio (95% CI)	p	Number needed to treat
Vocational or educational recovery					
Baseline	45 (62%)	56 (74%)	5.55 (1.09-28.23)	**0.04**	
18 months	47 (78%)	44 (70%)			
Hospital admissions due to mental health issues	12 (22%)	17 (31%)	0.46 (0.15-1.30)	0.15	11
Hospital admissions due to psychosis	7 (13%)	15 (27%)	0.36 (0.11-1.08)	0.07	7
Visits to emergency services	10 (19%)	21 (39%)	0.31 (0.11-0.86)	**0.03**	5

TAU – treatment as usual. Significant differences are highlighted in bold prints

and exclusion criteria employed to ensure the safety of the trial (i.e., clinical remission) could have led to a sample of higher functioning individuals at baseline[6].

Second, the sustained level of functioning in the TAU group could be accounted for by the quality and intensity of TAU following EPPIC treatment, which included follow-up treatment options such as multidisciplinary youth mental health services (e.g., headspace services) as well as government-subsidized psychological and psychiatric treatment.

Taken together, the higher baseline social functioning and shorter DUP in our cohort, coupled with the availability of publicly funded youth mental health support post-discharge from EPPIC, could have reduced the likelihood of finding group differences in social functioning over time. On the other hand, it could be that Horyzons is not effective enough in improving social functioning in this population, or that a different treatment modality, different or additional therapeutic targets, or a minimal threshold or a specific pattern of usage, are needed to demonstrate improved social functioning at follow-up.

The last above postulate is supported by our examination of the relationship between patterns of usage of Horyzons and outcomes. This analysis revealed that Horyzons users who showed consistent engagement with the social and therapeutic components of the digital platform experienced significant improvements in social functioning and negative symptoms compared with those with lower usage and those allocated to the TAU group (after controlling for potential confounders)[41].

A key finding of this study was that vocational/educational outcome improved significantly in the Horyzons plus TAU group compared with the TAU group, which deteriorated over the same period. Of note, *post-hoc* analyses provided evidence of a dose-response effect, with those participants in the top quartile of logins (i.e., logging on >77 times) showing a greater improvement on vocational and educational recovery (OR=59.71; 95% CI: 2.40-1484.37, p=0.01) compared with those in the bottom quartile of logins (i.e., <9 logins) (OR=1.40; 95% CI: 0.03-72.40, p=0.87).

This study is the first to demonstrate that extending the duration of support following specialist FEP services leads to improved vocational/educational outcome over a prolonged follow-up period. This finding has significant treatment and recovery implications. The extant evidence indicates that the positive effects of face-to-face Individual Placement and Support in FEP may wane after the intervention period[5]. Moreover, securing and maintaining employment and completing education remain a top priority for young people with psychosis, are critical aspects of mental health recovery and normative development, and constitute a protective factor against mental ill-health[42]. This study shows for the first time that a digital intervention integrating support by vocational workers and evidence-based vocational content is an effective strategy to address this critical treatment goal and potentially extend the benefits of existing evidence-based interventions in this population.

The study results provide support for the effect of Horyzons in reducing the rate of hospital admissions following discharge from specialist FEP services. While the difference with respect to the TAU group did not reach the level of statistical significance (p=0.07), the differential rate is evident (13% vs. 27%), and the low event rates significantly reduced the statistical power for this analysis. The clinical validity of this finding is strengthened by the associated finding that participants allocated to the TAU group were twice as likely to visit emergency services during the follow-up compared to those in the Horyzons group (39% vs. 19%, p=0.03). Of note, there were a total of 12 repeated visits to emergency services from seven different participants, all of which occurred in the TAU group.

It may be that Horyzons acts on distress, reducing utilization of emergency services and hospital admissions through in-the-moment access to online therapy, and peer and social support. This is in line with previous research showing that social support is associated with reduced risk of relapse in FEP[1]. The estimated NNT for Horyzons to prevent one visit to emergency services and one hospital admission were 5 and 7, respectively. This is comparable with the reported NNT for specialist FEP programs to prevent one relapse (NNT=8) and somewhat lower than the NNT with second-generation antipsychotics to prevent one relapse (NNT=10)[2].

Our exploratory analysis showed lower levels of negative symptoms from baseline to 12 months in the Horyzons group compared with the TAU group. This effect, however, was lost at 18-month follow-up. Malla et al[10] found that extending the duration of specialist FEP services was associated with improved negative symptoms at 5-year follow-up compared with TAU. In addition, similar to our findings, Chang et al[8] found a reduction in negative symptoms following one year of extended specialist FEP treatment which was

lost at 2- and 3-year follow-up. Our results suggest that Horyzons may have time-limited favorable effects on negative symptoms, corresponding with the period of higher usage of the program.

We did not find evidence for the effectiveness of Horyzons on other secondary outcome variables such as depression, social support, loneliness and quality of life. Several explanations may account for the lack of treatment effects on these variables. First, it is likely that bringing about treatment effect on specific outcome variables (e.g., depression) requires intensive, focused engagement of specific targets (e.g., rumination or behavioural activation[5,6]). Second, Horyzons is one of the first interventions harnessing social networking to promote both engagement and social support. However, we found that, whereas many young people had positive experiences of social connection on Horyzons, others experienced barriers (such as social anxiety, paranoia and confusion within the social network) that thwarted their need for connection with others[43]. Further research is required to determine the optimal features and operations of online social media-based interventions so that they support connectedness, whilst addressing barriers to meaningful engagement.

With the aim of sustaining the benefits of specialist FEP services, Horyzons was delivered for a period of 18 months. This approach is unique in the field of mental health. Typically, online interventions are provided for a median period of 10 weeks[44]. Sustained engagement has been recognized as a long-standing problem, with many patients failing to complete more than one or two sessions in self-guided online interventions, even with weekly telephone support[45]. With the aim of maximizing long-term engagement, the design of Horyzons exploited online social media technology, applied strengths-based approaches and drew on the self-determination theory. Encouragingly, our results showed that 80.2% of Horyzons users logged on for at least 3 months, 47.0% for 9 months or longer, and 29.0% for at least one year. These findings demonstrate the appeal of Horyzons in a difficult to engage cohort.

This study has several strengths. All research assessors and online therapists received regular supervision, including routine checks on interrater reliability and adherence to the therapy model. Significant efforts were made to maintain the masking of group assignment, and we confirmed that blinding was successful. The intervention was delivered in a clinical setting, increasing the clinical validity and generalizability of study methods and results.

The study also has some limitations. First, engagement with Horyzons over the 18-month intervention varied significantly amongst participants, which may moderate treatment efficacy. Moreover, the trial was by necessity single-blind, which may have had an impact on the results. Finally, we cannot rule out the possibility that the outcome of randomization influenced somewhat the discharge process, with young people allocated to the TAU group receiving a more careful discharge plan compared to those in the Horyzons group.

In conclusion, this is the first study to investigate whether a digital intervention is an effective approach to sustaining the benefits of specialist FEP services. While our results did not provide evidence to support the effectiveness of Horyzons in improving social functioning in FEP, baseline functioning was high in our cohort and, contrary to our expectations, remained high in both groups throughout the study. On the other hand, Horyzons was effective in improving vocational/educational attainment (a core aspect of social recovery), reducing visits to emergency services and reducing rates of hospital admissions due to psychosis following discharge from a specialist FEP service (a core target of specialized FEP services). Finally, our data demonstrated that Horyzons was appealing for young people with FEP, with many participants being engaged for sustained periods of time.

Horyzons has now been adapted and successfully piloted in specialized FEP services in the US[46] and Canada[47], with clinical implementation efforts underway in both countries as well as Australia. Ultimately, with specialized FEP services now being available across the US, Canada, Europe, Asia and Australasia, Horyzons holds significant promise as a novel, engaging and sustainable intervention to improve vocational recovery, reduce utilization of emergency services and provide continuous support for young people with FEP beyond specialized care.

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