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Complete List of Authors:	Thabrew, Hiran; The University of Auckland, Department of Psychological Medicine; Auckland District Health Board Boggiss, Anna; The University of Auckland, Department of Psychological Medicine Lim, David; The University of Auckland, Department of Psychological Medicine Schache, Kiralee; Counties Manukau District Health Board Morunga, Eva; Auckland District Health Board Cao, Nic; Counties Manukau District Health Board Cavadino, Alana; The University of Auckland, Department of Epidemiology and Biostatistics Serlachius, Anna; The University of Auckland, Department of Psychological Medicine
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A well-being app to support young people during the COVID-19 pandemic: randomised controlled trial

Authors

Hiran Thabrew[1,2], Child and Adolescent Psychiatrist, Paediatrician, Senior Lecturer, h.thabrew@auckland.ac.nz (corresponding author)

Anna Boggis[1], PhD Student, abog579@aucklanduni.ac.nz

David Lim[1], Masters Student, david_lim@tutunota.com

Kiralee Schache[3], Health Psychologist, kiralee.schache@middlemore.co.nz

Eva Morunga[2], Health Psychologist, emorunga@adhb.govt.nz

Nic Cao[3], Health Psychologist, n.cao@auckland.ac.nz

Alana Cavadino[4], Biostatistician, a.cavadino@auckland.ac.nz

Anna Serlachius[1], Health Psychologist, Senior Lecturer, a.serlachius@auckland.ac.nz

Affiliations

[1] Department of Psychological Medicine, Faculty of Medical and Health Sciences, The University of Auckland, New Zealand

[2] Auckland District Health Board, Auckland, New Zealand

[3] Counties Manukau District Health Board, Auckland, New Zealand

[4] Department of Epidemiology and Biostatistics, Faculty of Medical and Health Sciences, The University of Auckland, New Zealand

Contact details for corresponding author

Dr Hiran Thabrew, Department of Psychological Medicine, The University of Auckland, Auckland, New Zealand. Email: h.thabrew@auckland.ac.nz. Tel: +64 9 923 3073.

Author contributions

All authors contributed to the design, development and execution of the study. This paper was drafted by HT, AS and AC and reviewed by all other authors prior to submission to the BMJ.

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Data sharing

The deidentified dataset is available on request from the corresponding author: h.thabrew@auckland.ac.nz.

Abstract

Objectives: To evaluate the efficacy and acceptability of 'Whitu: seven ways in seven days', a well-being application (app) for young people.

Design: Prospective randomised controlled trial of Whitu against waitlist control, with 45 participants in each arm.

Participants: 90 New Zealand young people aged 16-30 recruited via a social media advertising campaign.

Setting: Participants' homes.

Interventions: Developed during the COVID-19 pandemic, 'Whitu: seven ways in seven days' is a well-being app that, as its name suggests, contains seven modules to help young people (i) recognise and rate emotions, (ii) learn relaxation and mindfulness, (iii) practice self-compassion and (iv) gratitude, (v) connect with others, (vi) care for their physical health and (vii) engage in goal-setting. It can be completed within a week or as desired.

Main outcome measures Primary outcomes were changes in well-being on the World Health Organisation 5-item well-being index (WHO-5) and short Warwick-Edinburgh mental well-being scale (SWEMWBS). Secondary outcomes were changes in depression on the Centre for Epidemiological Studies Depression Scale (CES-D), anxiety on the Generalised Anxiety Disorder seven item scale (GAD-7), self-compassion on the Self Compassion Scale- Short Form (SCS-SF), stress on the 10-item Perceived Stress Scale (PSS-10) , sleep on the single-item Sleep Quality Scale (SQS) and user engagement on the end-user version of the Mobile Application Rating Scale (uMARS) and via qualitative feedback. Outcomes were evaluated at baseline, four weeks (primary study endpoint) and three months, and analysed using linear mixed models with group, time and a group-time interaction.

Results: At 4 weeks, participants in the Whitu group experienced significantly higher emotional (Mean difference (md) 12.93 (3.70, 22.15); p=0.006) and mental (md 2.41 (0.22,

4.59); p=0.031) well-being, self-compassion (md 0.54 (0.26, 0.82); p<0.001) and sleep (md 1.08 (0.19, 1.98); p=0.018), and significantly lower stress (md -4.77 (-7.75, -1.79); p=0.002) and depression (md -5.66 (-10.48, -0.83); p=0.022), compared to the waitlist controls. Group differences remained statistically significant at 3 months for all outcomes except sleep (p=0.056). Symptoms of anxiety were also lower in the intervention group at 4 weeks (p=0.073), with statistically significant differences at 3 months (md -2.46 (-4.70, -0.23); p=0.031). Usability of Whitu was high (subjective ratings of 4.45 (0.72) and 4.38 (0.79) out of 5 at 4 weeks and 3 months respectively) and qualitative feedback indicated individual and cultural acceptability of the app.

Conclusions: Given the evolving psychological burden of the COVID-19 pandemic, Whitu could provide a clinically effective and scalable means of improving the well-being, mental health and resilience of young people. Replication of current findings with younger individuals and in other settings is planned.

Trial Registration: This study was registered with the Australian New Zealand Clinical Trials Network Registry: ACTRN12620000516987

Keywords:

COVID-19; pandemic; mental health; mobile apps; mHealth; coping skills; well-being; adolescent; young adult

Article Summary

Strengths and limitations of this study

- This study is the first to demonstrate the effectiveness of a free, scalable eHealth app ('Whitu') for improving multiple aspects of well-being and mental health in young people during the COVID-19 pandemic.
- Whitu demonstrated good usability and general and cultural acceptability with its intended audience.

- As it was undertaken with a community sample of New Zealand young people, the findings of this randomised controlled trial require replication to confirm their generalisability to other groups and settings.

Introduction

The 'invisible pandemic' of psychological issues associated with COVID-19 is only beginning to be realised [1,2]. Young people are particularly vulnerable to developing such issues due to pre-existing mental health challenges[3] and lockdown-related disruption of their developmentally-related needs [4]. Within the past year, increased rates of mental distress [5], anxiety [6], depression [7-9] and suicidal ideation [10] have already been identified among young people in multiple countries. Additionally, those who have contracted COVID-19 have reported high rates of post-traumatic stress disorder [11]. Long-term adverse health, academic and occupational consequences of these psychological issues are likely [3,7,12,13], especially in previously recognised subgroups with greater health needs [11,14]. Despite increased demand for psychological support, access to face to face services has been significantly disrupted and delayed[15,16]. Furthermore, evidence-based interventions for preventing and addressing psychological issues related to the pandemic are rare [17].

Over the past decade, an increasing body of research has demonstrated the effectiveness of digital mental health interventions at improving the well-being and mental health of young people [18-20]. This has led to some being recommended as first line treatments for conditions such as depression by the National Institute for Clinical Excellence (NICE) in the UK [21]. Given the frequency of smartphone use by young people [16], mobile health applications (apps) have particular appeal as a means of supporting young people to safely and conveniently learn and practice skills in the real world [15,16,18,19]. However, out of over 20,000 available mobile health apps, very few have evidence of efficacy [22]. Since the onset of the pandemic, the demand for mobile health apps has considerably increased [23] and policy makers have recognised them as a widely disseminable means of improving immediate and longer-term well-being [24].

Prior to the pandemic, New Zealand young people were experiencing high levels of mental distress, depression and the highest suicide rate among developed countries [25-28]. Due to concerns about these issues becoming significantly worse in the context of mandated social distancing and repeated lockdowns, our research team rapidly developed an app to support the emotional well-being of this group, with special emphasis on the needs of young people of Māori and Pacific ethnicity who had always been disproportionately affected by mental health issues [15,16]. 'Whitu: seven ways in seven days' (Whitu meaning seven in the NZ Māori language 'Te Reo') was based on a range of cognitive behavioural therapy (CBT), psychoeducation, and positive psychology techniques previously shown to have efficacy in young people [15,16,18]. The development of Whitu is discussed in more detail in our protocol paper [29]. A small pilot trial (n=20) of the prototype app demonstrated statistically significant within-group improvements in well-being (p=.021), anxiety (p=.005), depression (p=.031) and stress (p=.004) between baseline and 6-weeks, but no significant changes in self-compassion, or sleep (in press, data available from the authors on request). User feedback led to improvements being made to the look and feel, cultural content and onboarding experience. This randomised controlled trial was undertaken to evaluate the efficacy, usability and acceptability of the refined version of the app. We hypothesised that, compared with a wait-list control group, users of Whitu would experience improved well-being, self-compassion, sleep, and reduced stress, anxiety and depression at four weeks and three months. Secondarily, we hypothesised that Whitu would be usable and acceptable to young people.

Methods

Study design

A mixed methods approach was used to determine the efficacy, usability and acceptability of 'Whitu'. The study was prospectively registered with the Australian New Zealand Clinical Trials Registry (ACTRN12620000516987) and received ethics approval from the University of Auckland Human Participant Ethics Committee (Reference 024542).

Participants

New Zealand residents aged between 16 and 30 years who had reliable access to Wi-Fi, owned either an iPhone or Android mobile phone, were not currently receiving mental health treatment, and could read and understand enough English to use the app via an online social media advertising campaign were recruited for the study. Participants were provided with a NZD $40 (GBP 20) gift voucher on exit from the study as a thank you for their time.

Procedures

Participants (i) read study information, (ii) completed informed consent procedures and baseline questionnaires, and (iii) were randomised to either the intervention group (Whitu app) or wait-list control group via REDCap®, a secure web application. Due to the nature of the study, neither participants nor researchers were blinded to treatment allocation. The intervention group was encouraged to download and use the app for four weeks. Both groups completed outcome measures via REDCap® at four weeks and three months, following which control group participants were also provided with the app. No outcome measures were collected beyond this point. Further details are provided in our study protocol [29].

Intervention

Whitu: seven ways in seven days is a free mobile application (app) that is currently available to New Zealand users via the App Store (https://apps.apple.com/nz/app/whitu/id1508135602?ign-mpt=uo%3D4) and Google Play Store (https://play.google.com/store/apps/details?id=com.carbonimagineering.whitu). It contains seven positive psychology, CBT and psychoeducation-based modules that can be completed within a week. Users are encouraged to choose from a broad range of strategies and discover the ones that best work for them. Badge rewards and daily notifications encourage app completion and practice of preferred strategies. Further details of the app are provided in Table 1 and Figure 1. No user information or app analytic data are collected or stored over the Internet. Data entered by users are stored on their devices in an unencrypted SQLite database and can be safely removed at any time by deleting the app.

Table 1: The seven modules of Whitu

Module 1: Feel	The first module acknowledges that young people may be feeling low and struggling with negative emotions due to the pandemic. The module introduces the concept of identifying and monitoring emotions, and identifying adaptive and maladaptive coping skills.
Module 2: Relax	The second module addresses the uncertainty and stress that young people may be feeling due to the pandemic. Users are introduced to relaxation techniques such as deep breathing, progressive muscle relaxation, and guided visualization.
Module 3: Be kind to yourself	The third module introduces the concept of self-compassion and users are guided through a short meditation and self-kindness writing exercise.
Module 4: Be thankful	The fourth module introduces the concept of gratitude and how it is linked to positive wellbeing. Users are encouraged to create and use a diary or photographic record of things for which they are grateful.
Module 5: Connect	The fifth module addresses the negative impact that lockdowns and physical distancing can have on relationships. Users are encouraged to identify important people in their lives and practice ways of staying connected with them.
Module 6: Look after your body	The sixth module discusses how the pandemic makes it more difficult to stay active and look after our bodies. Users are encouraged to eat more healthily, identify and use available forms of exercise and practice good sleep hygiene.

Module 7: Set goals	The final module acknowledges that the pandemic has probably interrupted routines and made it harder to set healthy goals. User are introduced SMART goals and encouraged to practice setting and achieving at least one such goal.

Figure 1: Images of Whitu modules, including activities and badges

Outcomes

Demographic data, including sex, age, and ethnicity, were collected from all participants via REDCap® at baseline. Outcome measures were assessed at baseline, four-week and three-month follow-up, with emotional and mental well-being outcomes at 4-weeks being the primary endpoints. Emotional well-being was measured using the 5-item World Health Organisation Well-Being Index (WHO-5) [30]. Mental well-being was measured by the seven-item Short Warwick-Edinburgh Mental Well-being Scale (SWEMWBS) [31,32]. The scale has demonstrated good reliability (α=.84) and validity in adolescent and young adult populations [33,34]. Depression was measured by the 20-item Center for Epidemiological Studies Depression Scale (CES-D) [35]. The CES-D demonstrates high correlations with other depression measures and excellent internal consistency (α=.85) [35]. Anxiety was measured by the Generalised Anxiety Disorder 7-item Scale (GAD-7) [36]. The scale has demonstrated excellent reliability (α=.92) and validity in adults [37] and adolescents [38]. Self-compassion was measured by the Self-Compassion Scale-Short Form (SCS-SF) [39]. The scale has demonstrated good reliability (α >.86) in an adolescent sample [40]. Stress was measured by the 10-item Perceived Stress Scale (PSS-10) [41,42]. The PSS-10 scale has demonstrated excellent psychometric properties compared to other stress measures, with good reliability and validity [43]. Sleep quality was measured by the single-item Sleep Quality Scale (SQS) [44]. The SQS has been shown to have excellent concurrent and convergent validity with other lengthier sleep scales and has been demonstrated to be effective in determining clinically meaningful changes in sleep quality. User engagement was assessed by the app Subjective Quality

subscale and the Perceived Impact subscale of the end-user version of the uMARS measure [45]. The Subjective Quality subscale score consists of four items that determine user experience (e.g., Would you pay for this app?"). The Perceived Impact subscale score is derived from 6 items measuring the impact of using the app on knowledge, attitudes, and intentions. The uMARS demonstrates good internal reliability (α=.90), and the subscales demonstrate moderate reliability (α=.71 and .80) [45]. In addition to the uMARS, participants also answered how many modules of the *Whitu* app they completed at each time point (1-7 modules) and provided brief qualitative feedback about their experience of using the app via an open-ended question in REDCap®.

Data Analysis

Using Gpower [46], we estimated a sample size of 90 participants (45 per treatment arm) would provide an effect size of f=0.155 [47] for between group improvement in well-being using the WHO-5 index using a mixed analysis of variance (ANOVA) including within (three time points) and between (two groups) subject effects, with 90% power and at a two-sided significance level of 5%. To ensure cultural acceptability of the app, we planned to recruit at least 36 (40%) young people of Māori and Pacific Island ethnicity. Baseline characteristics were summarized using means and standard deviations or numbers and percentages. Repeated measures ANOVA was used with linear mixed models to include participants with data at only two of the three time points. The main analysis aimed to determine whether changes in psychological outcomes were the result of the interaction between the intervention group and time, with post-hoc tests to assess pairwise comparisons of groups at each time point and within-group changes over time. Cohens f^2 was calculated as a measure of effect size for the group by time interaction [48]. The primary comparisons of interest were between group differences at 4 weeks and 3 months, with results presented as marginal mean

differences, 95% CIs and p-values. Data from participants who reported completing at least baseline and one follow-up outcome measure were analysed on an intention-to-treat basis. Data was analysed using Stata® software version 17, and statistical significance was set at $p<0.05$. Qualitative feedback was independently extracted and analysed by two authors (HT and AS) using directed content analysis [49]. Data was examined to the point of thematic saturation and any discrepancies in coding were resolved by consensus.

Patient and Public Involvement

Whitu was actively co-designed with New Zealand young people during the COVID-19 pandemic [29]. However, no patients were involved in setting the research question or in developing plans for recruitment, design, implementation and dissemination of the results of the study.

Results

Participant characteristics

Of the 299 individuals who expressed interest, 90 eligible participants were recruited to the study (45 per arm) between November 2020 and January 2021. Two participants withdrew from the intervention arm without using the app due to technical difficulties or choice, four from the same arm were lost to follow-up at four weeks and another at three months. Only one participant was lost from the control arm at four weeks. Further details are presented in the CONSORT flow diagram (Figure 2).

Figure 2: CONSORT flow diagram

Participants ranged between 16 and 30 years, with a mean age of 23.6 years (SD 3.8). The majority of participants were female (n=74; 87.1%) and were students (n=57; 67.1%). Around a third reported having chronic health conditions including anorexia, anxiety, asthma, bipolar disorder, depression, eczema, epilepsy, hay-fever, hyperthyroidism, insomnia, migraines and polycystic ovarian syndrome. Participant demographics were similar between the intervention and control arm. Further details are presented in Table 2.

Table 2: Participant demographics

Characteristics	Whitu app (N=40)	Waitlist control (N=45)	Total (N=85)
Age (years); mean (SD)	22.33 (3.47)	24.64 (3.74)	23.56 (3.78)
Gender			
Female	35 (87.5%)	39 (86.7%)	74 (87.1%)
Male	3 (7.5%)	6 (13.3%)	9 (10.6%)
Non-binary	2 (5.0%)	0	2 (2.4%)
Ethnicity *			
New Zealand European	12 (30.0%)	11 (24.4%)	23 (27.1%)
Māori	19 (47.5%)	17 (37.8%)	36 (42.4%)
Pacific	2 (5.0%)	9 (20.0%)	11 (12.9%)
Asian	5 (12.5%)	4 (8.9%)	9 (10.6%)
Other ethnic groups	2 (5.0%)	4 (8.9%)	6 (7.1%)
Occupation			
Paid work	13 (32.5%)	15 (33.3%)	28 (32.9%)
Student	27 (67.5%)	30 (66.7%)	57 (67.1%)
Reported having a health condition	17 (42.5%)	12 (26.7%)	29 (34.1%)
Reported taking medications	14 (35.0%)	6 (13.3%)	20 (23.5%)
Reported previous related app use**	9 (22.5%)	11 (24.4%)	20 (23.5%)

*Data are displayed as N (%), unless otherwise stated. *Pacific including: Samoan (n=6), Tongan (n=4), Fijian/Tuvaluan (n=1); and Asian including: Chinese (n=3), Indian (n=3), NZ Sri-Lankan (n=1), Indonesian (n=1), Taiwanese (n=1); **Apps previously used included Calm (n=7), Headspace (n=12) and Insight (n=1)*

Changes in outcome measures over time

Results presented in Table 2 demonstrate that the intervention had a significant effect, as observed by a significant time by group interaction, on emotional (p=0.04) and mental (p=0.008) well-being, stress (p=0.002) and self-compassion (p=0.002). Measures of well-being and self-compassion were significantly higher and stress was significantly lower in the intervention group at both the 4-week and 3-month follow-up. The interaction between group and time on depression, anxiety and sleep did not reach statistical significance. However, differences between groups indicated evidence of better outcomes for those in the intervention group, with lower levels of depression (significant at both follow-ups) and anxiety (significant at 3-months) and higher sleep scores (significant at 4 weeks) being observed, compared to the waitlist controls. All outcome measures significantly improved over time within the intervention group ($p<0.05$; supplementary Table 1). There were no significant differences in outcome measures over time in the waitlist control group, except for sleep scores, which were higher at both follow-ups compared to baselines, although the effects were smaller compared to the intervention group (supplementary Table 1). Further details are presented in Table 3, Supplementary Table 1 and Supplementary Figure 1.

Table 3: Comparisons between groups in outcome measures over the study period

Outcome	Whitu app (N=40) Mean (SD)	Waitlist control (N=45) Mean (SD)	Mean difference Whitu vs control (95% CI)	*P value*	*Group by time interaction P value*	*Cohen's f^2 effect Size*
Emotional well-being (WHO-5)						
Baseline	49.60 (19.40)	46.84 (23.78)	2.76 (-6.43, 11.94)	0.556		
4 weeks	55.28 (23.03)	42.13 (21.02)	12.93 (3.70, 22.15)	**0.006**	**0.038**	*f^2 = 0.050*
3 months	60.51 (18.70)	47.09 (22.74)	13.50 (4.24, 22.76)	**0.004**		
Mental well-being (SWEMBS)						
Baseline	22.30 (4.99)	22.24 (5.16)	0.06 (-2.12, 2.23)	0.960		
4 weeks	24.69 (4.98)	22.27 (5.04)	2.41 (0.22, 4.59)	**0.031**	**0.008**	*f^2 = 0.077*
3 months	24.58 (4.95)	21.70 (5.47)	2.98 (0.77, 5.18)	**0.008**		
Depression (CES-D)						
Baseline	20.18 (12.44)	22.31 (11.51)	-2.14 (-6.94, 2.67)	0.384		
4 weeks	15.72 (10.15)	21.56 (11.54)	-5.66 (-10.48, -0.83)	**0.022**	0.081	*f^2 = 0.048*
3 months	16.26 (9.42)	23.07 (12.15)	-6.94 (-11.77, -2.12)	**0.005**		
Anxiety (GAD-7)						
Baseline	9.13 (5.82)	9.42 (5.36)	-0.3 (-2.52, 1.92)	0.793		
4 weeks	6.54 (4.76)	8.56 (5.74)	-2.04 (-4.27, 0.19)	0.073	0.081	*f^2 = 0.046*
3 months	6.05 (4.22)	8.48 (5.15)	-2.46 (-4.70, -0.23)	**0.031**		
Stress (PSS-10)						
Baseline	21.70 (7.42)	21.62 (7.07)	0.08 (-2.89, 3.05)	0.959		
4 weeks	16.62 (6.34)	21.42 (7.24)	-4.77 (-7.75, -1.79)	**0.002**	**0.002**	*f^2 = 0.106*
3 months	17.33 (6.32)	21.41 (7.29)	-3.92 (-6.92, -0.93)	**0.010**		
Self-compassion (SCS-SF)						
Baseline	2.74 (0.66)	2.69 (0.60)	0.05 (-0.22, 0.33)	0.696	**0.002**	*f^2 = 0.095*

4 weeks	3.21 (0.55)	2.68 (0.66)	0.54 (0.26, 0.82)	**<0.001**		
3 months	3.11 (0.73)	2.82 (0.66)	0.30 (0.02, 0.57)	**0.036**		
Sleep (SQS)						
Baseline	5.13 (1.99)	4.84 (2.17)	0.28 (-0.61, 1.17)	0.537		
4 weeks	6.90 (1.93)	5.82 (2.23)	1.08 (0.19, 1.98)	**0.018**	0.123	$f^2 = 0.085$
3 months	7.05 (1.85)	6.14 (2.31)	0.88 (-0.02, 1.77)	0.056		

User feedback

Overall, feedback regarding the app was positive, with special mention made of features designed to increase cultural appeal such as the introductory 'karanga' (welcome song). Participants expressed diverse preferences regarding individual modules, with newly learnt content being most valued. Suggestions for improvement included the use of shorter videos, improved navigation and greater flexibility with reminders (currently set at once per day). Six users with older mobile phones experienced some technical difficulties, but were still able to use the app. Key themes and examples of participant feedback are provided in Table 4. Usability scores for Whitu are also provided in Table 5.

Table 4: Participant feedback

Theme	Examples
Most useful modules or features	"I found the relax one most helpful. I just really enjoy the guided meditation aspect, the main thing that draws me to these apps. Lovely app, will definitely use again" (Participant 346) "I found the 'be thankful' module the most helpful. I liked this one as it made me stop and consciously focus on the positive aspects of my life" (Participant 327) "This is a well-thought out app and will go on to help many individuals like myself. I feel like i should make a special mention of the karanga at the beginning of the app when i first opened and downloaded it. As a young Māori woman, being called into the app and have it welcome all my problems and grief instantly sparked a

	spiritual connection for me and i instantly felt at ease and felt safe enough to embark on my healing and wellbeing journey. I also enjoyed the constant use of Te Reo Māori and the progress of watching my Puriri tree grow throughout the 4 weeks. It was a pleasant surprise and so culturally inclusive. The voice overs were pleasant to listen to, the videos, sounds and effects captivating. The best app after what was such a rollercoaster year! Thank you!" (Participant 376)
Suggestions for improvement	"Make the videos shorter somehow, I think young people nowadays have short attention spans... including me" (Participant 308) "I did find it was sometimes tricky to find the follow up activities I was supposed to do - these could be better signposted/reminders could link to them directly" (Participant 354) "The daily reminder is good, but often came at a time when I was busy! Maybe a second reminder or setup as part of a daily routine" (Participant 333)
Technical difficulties	"On old phone, when completing modules there was graphical glitching (buttons and images being in the wrong place, the background video overlay being stuck in place between menus).There was also some issues with the video. Sometimes it just wouldn't play until I restarted the app" (Participant 335) "Now that I check the app it has logged my progress with Module 2 but I did not find that right after I had completed it" (Participant 337)

Table 5: Usability for n=38 participants in the intervention group using the Whitu app*

Measures	4 weeks (N=38**)	3 months (N=37**)
uMARS (score range 1-5)		
Subjective app quality score	4.45 (0.72)	4.38 (0.79)
Perceived impact: Awareness	3.89 (0.95)	4.00 (1.03)
Perceived impact: Knowledge/understanding	3.76 (1.15)	3.86 (1.03)
Perceived impact: Attitudes	3.58 (1.13)	3.46 (1.28)
Perceived impact: Intention to change	3.71 (1.09)	3.57 (1.34)
Perceived impact: Help seeking	3.66 (1.07)	3.57 (1.07)
Perceived impact: Behavior change	3.63 (1.10)	3.76 (1.19)

Overall findings

To our knowledge, this is the first randomised controlled trial of a well-being app for young people undertaken during the COVID-19 pandemic and it addresses the clear gap in the COVID-related literature (i.e. the lack of studies to address anticipated psychological effects of the pandemic) highlighted by Gilbody et al [50]. Our results indicate that Whitu is an effective, usable and acceptable composite digital health intervention with which to improve multiple aspects of young people's health including well-being, self-compassion, and sleep, and to reduce anxiety, depression and stress. Clinical benefits were evident at four weeks and sustained at three-month follow-up. Based on uMARS scores (Table 4), usability of Whitu was high, and greater than that of recently developed mental health apps and established norms [51,52].

Our findings are consistent with recent review evidence that mindfulness and multi-component interventions are most effective at improving the well-being of clinical and non-clinical populations [53]. Despite the potential floor effect with a non-clinical population, users of Whitu reported significantly improved symptoms of anxiety and depression. Resulting effect sizes were similar to the small to moderate effect sizes of individually-targeted digital interventions for treating these conditions [54], suggesting that Whitu may be beneficial for clinical populations. Since the onset of the pandemic, a rapid review of existing digital mental health interventions has ascertained they are usable, safe, acceptable and likely to be effective in ameliorating at least some of the psychological consequences of lockdown [54]. However, only one other RCT of a four-week mindfulness-based intervention delivered to Chinese university students via Zoom® and asynchronous WeChat video and audio recordings has actually been undertaken and shown to improve symptoms of anxiety and depression compared with technology-based social support [55].

Given reports that only 3.9% of individuals who download health apps use them for a median of 15 days more than two weeks [56] and that only 0.5 to 28.7% actually complete them [57], the relatively high efficacy and acceptability of Whitu may be related to its intentionally time-limited design. Encouraging young people to learn new self-management strategies via the app and then practice them in the real world should also help with generalisation of these skills [57]. Although some may argue that an app designed to support young people during the pandemic may be of limited chronological relevance, previous evidence from earthquake survivors in New Zealand suggests that psychological effects of major events are likely to be delayed, with rates of problems increasing by between 25-40% even after two year [58,59]. Given the protracted nature of the current pandemic, its true psychological cost will only be obvious in retrospect.

Strengths of this study include the adequate power, low drop-out rate (less than the typical drop-out rate of 25% during studies of other mobile health interventions) [60] and small amount of missing data. In addition, given our desire to develop a culturally safe and relevant app, the appeal of Whitu to Māori and Pacific young people and its efficacy with these groups is reassuring and likely to reduce existing health inequities, thereby honouring New Zealand's commitment to the Treaty of Waitangi [61,62]. Weaknesses of the study include limitation of enrolment to users over 16 years of age, lack of an active control group, inclusion of fewer male participants and use of self-reported outcome measures. Our results need to be replicated in other settings (such as schools) and with young people below 16 years of age. Evaluation of Whitu's efficacy with higher-risk groups such as young people with long-term physical conditions [16] and more objective measures of app use and clinical outcomes would be valuable. Finally, future research would benefit from formal economic analysis to bridge the gap between researcher interests and policymakers [63]. For the moment, this study

provides preliminary evidence that Whitu is a clinically effective and scalable means of improving the well-being and mental health of young people during the COVID-19 pandemic.

Author statement

HT, AS, EM, NC, AC, AB, K.S, and DL were involved in the design and implementation of the study. HT, AS, AB and AC were involved in quantitative data analysis. HT and AS were involved in qualitative data analysis. All authors were involved in drafting and reviewing the paper. The corresponding author is the guarantor and accepts full responsibility for the work and/or the conduct of the study, had access to the data, and controlled the decision to publish. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

Funding

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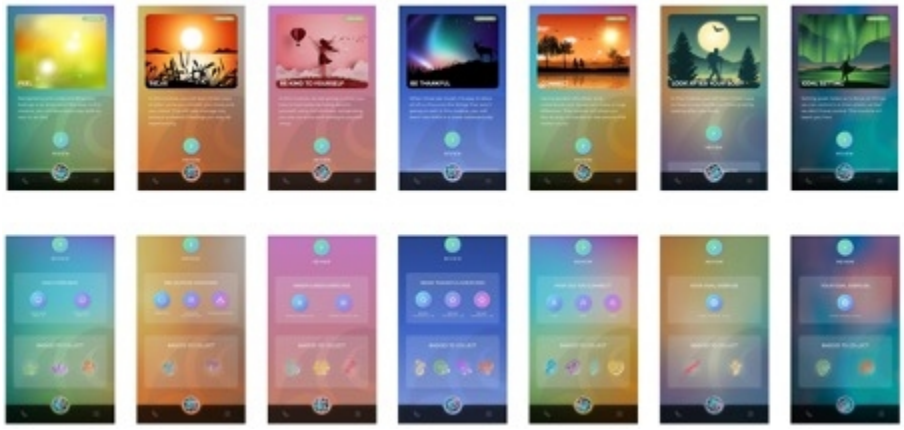

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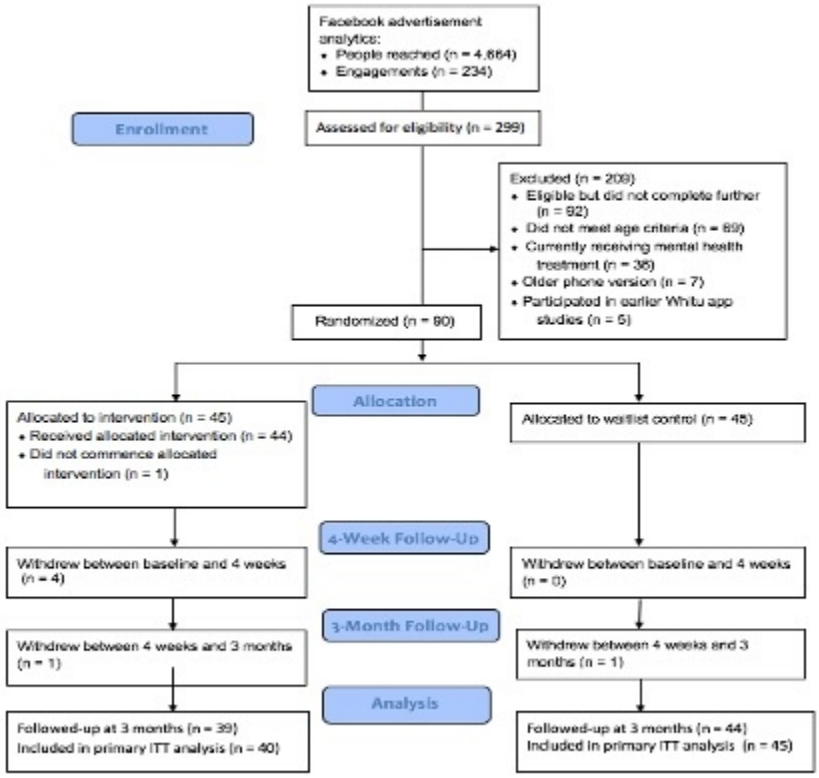

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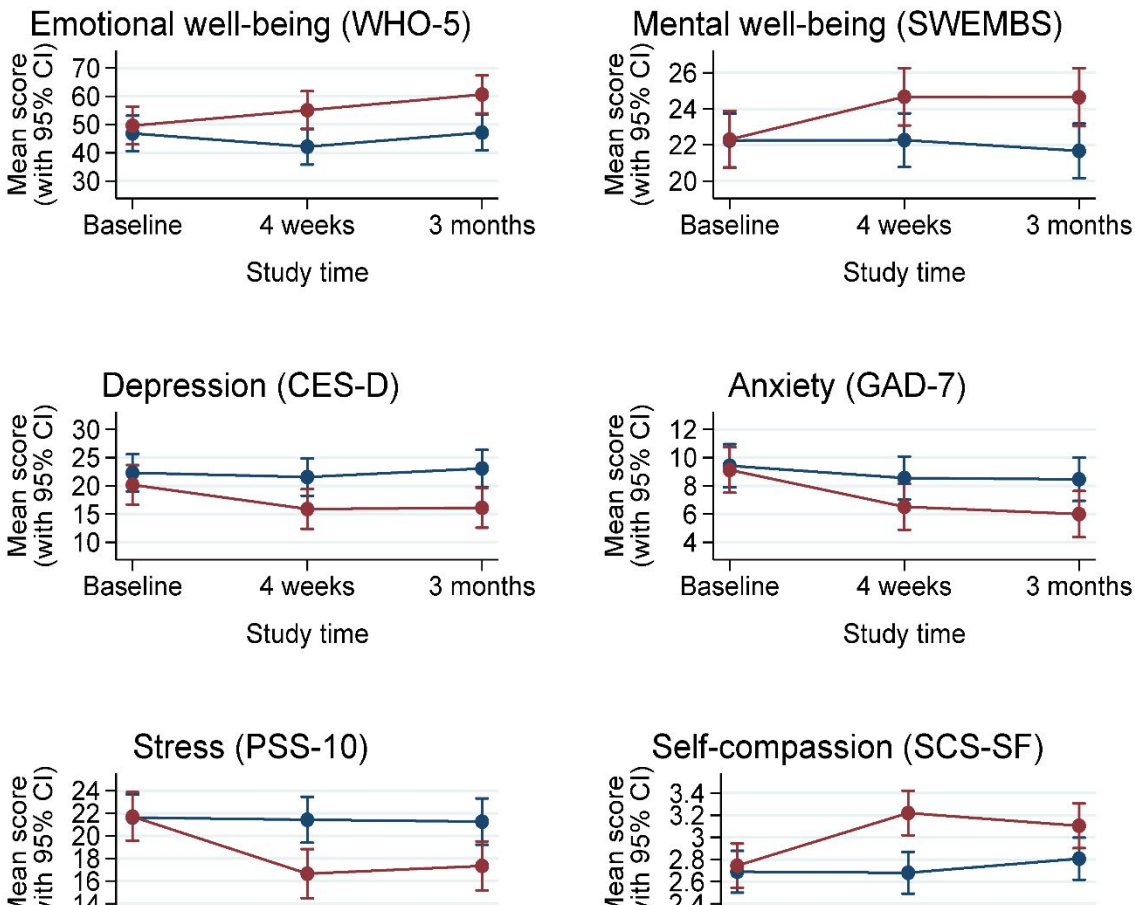
Supplementary table 1: Within group changes in outcome measures over time

Outcome	Whitu app *(N=40)*			Waitlist control (N=45)			*Group by time Interaction P value*
	Mean (SD)	Mean difference (95% CI)	*P value*	Mean (SD)	Mean difference (95% CI)	*P value*	
Emotional well-being (WHO-5)							
Baseline	49.60 (19.40)	Ref	Ref	46.84 (23.78)	Ref	Ref	
4 weeks	55.28 (23.03)	5.46 (-1.32, 12.24)	0.114	42.13 (21.02)	-4.71 (-11.05, 1.62)	0.145	**0.038**
3 months	60.51 (18.70)	11.04 (4.27, 17.82)	**0.001**	47.09 (22.74)	0.3 (-6.08, 6.68)	0.927	
Mental well-being (SWEMBS)							
Baseline	22.30 (4.99)	Ref	Ref	22.24 (5.16)	Ref	Ref	
4 weeks	24.69 (4.98)	2.37 (0.95, 3.79)	**0.001**	22.27 (5.04)	0.02 (-1.3, 1.35)	0.974	**0.008**
3 months	24.58 (4.95)	2.35 (0.92, 3.78)	**0.001**	21.70 (5.47)	-0.57 (-1.92, 0.77)	0.404	
Depression (CES-D)							
Baseline	20.18 (12.44)	Ref	Ref	22.31 (11.51)	Ref	Ref	
4 weeks	15.72 (10.15)	-4.28 (-7.46, -1.1)	**0.008**	21.56 (11.54)	-0.76 (-3.73, 2.22)	0.618	0.081
3 months	16.26 (9.42)	-4.05 (-7.23, -0.87)	**0.012**	23.07 (12.15)	0.76 (-2.22, 3.73)	0.618	
Anxiety (GAD-7)							
Baseline	9.13 (5.82)	Ref	Ref	9.42 (5.36)	Ref	Ref	
4 weeks	6.54 (4.76)	-2.61 (-4.07, -1.14)	**<0.001**	8.56 (5.74)	-0.87 (-2.23, 0.5)	0.214	0.081
3 months	6.05 (4.22)	-3.13 (-4.59, -1.66)	**<0.001**	8.48 (5.15)	-0.96 (-2.34, 0.42)	0.172	
Stress (PSS-10)							
Baseline	21.70 (7.42)	Ref	Ref	21.62 (7.07)	Ref	Ref	
4 weeks	16.62 (6.34)	-5.05 (-7.1, -2.99)	**<0.001**	21.42 (7.24)	-0.2 (-2.12, 1.72)	0.838	**0.002**
3 months	17.33 (6.32)	-4.36 (-6.42, -2.31)	**<0.001**	21.41 (7.29)	-0.36 (-2.3, 1.58)	0.716	

Self-compassion (SCS-SF)							
Baseline	2.74 (0.66)	Ref	Ref	2.69 (0.60)	Ref	Ref	
4 weeks	3.21 (0.55)	0.48 (0.28, 0.68)	**<0.001**	2.68 (0.66)	-0.01 (-0.2, 0.18)	0.922	**0.002**
3 months	3.11 (0.73)	0.36 (0.16, 0.56)	**<0.001**	2.82 (0.66)	0.12 (-0.07, 0.31)	0.214	
Sleep (SQS)							
Baseline	5.13 (1.99)	Ref	Ref	4.84 (2.17)	Ref	Ref	
4 weeks	6.90 (1.93)	1.78 (1.2, 2.36)	**<0.001**	5.82 (2.23)	0.98 (0.43, 1.52)	**<0.001**	0.123
3 months	7.05 (1.85)	1.92 (1.33, 2.5)	**<0.001**	6.14 (2.31)	1.32 (0.77, 1.87)	**<0.001**	

Supplementary Figure 1. Marginal mean outcomes by group and study time point



CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	1
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	5
	2b	Specific objectives or hypotheses	6
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	7
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	7
	4b	Settings and locations where the data were collected	7
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	8
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	9
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	10
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	7
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	7
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	7
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	7
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	7

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	N/A
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	10
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	11
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	12
	13b	For each group, losses and exclusions after randomisation, together with reasons	12
Recruitment	14a	Dates defining the periods of recruitment and follow-up	12
	14b	Why the trial ended or was stopped	N/A
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	13
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	14
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	15
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	15
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	16-17
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	14
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	19
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	19
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	19
Other information			
Registration	23	Registration number and name of trial registry	4
Protocol	24	Where the full trial protocol can be accessed, if available	4
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	20

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

TIDieR Template for Intervention Description and Replication

The TIDieR (Template for Intervention Description and Replication) Checklist*:

Information to include when describing an intervention and the location of the information

Item number	Item	Where located ** Primary paper (page or appendix number)	Other † (details)
	BRIEF NAME		
1.	Provide the name or a phrase that describes the intervention. **A well-being app to support young people during the COVID-19 pandemic**	1	
	WHAT		
2.	Describe any rationale, theory, or goal of the elements essential to the intervention. **A well-being app that, as its name suggests, contains seven positive psychology, CBT and psychoeducation-based modules to help young people (i) recognise and rate emotions, (ii) learn relaxation and mindfulness, (iii) practice self-compassion and (iv) gratitude, (v) connect with others, (vi) care for their physical health and (vii) engage in goal-setting. It can be completed within a week or as desired.**	6	
3.	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL). **Whitu: seven ways in seven days is a free-to-user mobile application (app) that is available on the App Store (https://apps.apple.com/nz/app/whitu/id1508135602?ign-mpt=uo%3D4) and Google Play Store (https://play.google.com/store/apps/details?id=com.carbonimagineering.whitu) for New Zealand residents.**	8	
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities. **Prospective randomised controlled trial of Whitu against waitlist control, with 45 participants in each arm. 90 New Zealand young people aged 16-30 recruited via a social media advertising**	6	

	campaign. Primary outcomes were changes in well-being on the World Health Organisation 5-item well-being index (WHO-5) and short Warwick-Edinburgh mental well-being scale (SWEMWBS). Secondary outcomes were changes in depression on the Centre for Epidemiological Studies Depression Scale (CES-D), anxiety on the Generalised Anxiety Disorder seven item scale (GAD-7), self-compassion on the Self Compassion Scale- Short Form (SCS-SF), stress on the 10-item Perceived Stress Scale (PSS-10) ,sleep on the single-item Sleep Quality Scale (SQS) and user engagement on the end-user version of the Mobile Application Rating Scale (uMARS) and via qualitative feedback. Outcomes were evaluated at baseline, four weeks (primary study endpoint) and three months, and analysed using linear mixed models with group, time and a group-time interaction.		
	WHO PROVIDED		
5.	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given. **N/A (self-help intervention (app) utilised without therapeutic support)**		
	HOW		
6.	Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group. **App downloaded onto participants' mobile phones and individually used.**	7_	
	WHERE		
7.	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features. **Intervention completed in participants' homes**.	7_	
	WHEN and HOW MUCH		
8.	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	7_	

	App designed to be flexibly used, but ideally completed within a week. Users given up to 4 weeks to complete the intervention.		
	TAILORING		
9.	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how. **Users could complete most modules in any order that they wished and repeat preferred exercises as often as desired.**	7	
	MODIFICATIONS		
10.‡	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how). **N/A**		
	HOW WELL		
11.	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them. **N/A (as the intervention was designed to be flexibly used, this was not relevant)**		
12.‡	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned. **N/A**		

** **Authors** - use N/A if an item is not applicable for the intervention being described. **Reviewers** – use '?' if information about the element is not reported/not sufficiently reported.

† If the information is not provided in the primary paper, give details of where this information is available. This may include locations such as a published protocol or other published papers (provide citation details) or a website (provide the URL).

‡ If completing the TIDieR checklist for a protocol, these items are not relevant to the protocol and cannot be described until the study is complete.

* We strongly recommend using this checklist in conjunction with the TIDieR guide (see *BMJ* 2014;348:g1687) which contains an explanation and elaboration for each item.

* The focus of TIDieR is on reporting details of the intervention elements (and where relevant, comparison elements) of a study. Other elements and methodological features of studies are covered by other reporting statements and checklists and have not been duplicated as part of the TIDieR checklist. When a **randomised trial** is being reported, the TIDieR checklist should be used in conjunction with the CONSORT statement (see www.consort-statement.org) as an extension of **Item 5 of the CONSORT 2010 Statement.** When a **clinical trial protocol** is being reported, the TIDieR checklist should be used in conjunction with the SPIRIT statement as an extension of **Item 11 of the SPIRIT 2013 Statement** (see www.spirit-statement.org). For alternate study designs, TIDieR can be used in conjunction with the appropriate checklist for that study design (see www.equator-network.org).

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A well-being app to support young people during the COVID-19 pandemic:randomised controlled trial

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A well-being app to support young people during the COVID-19 pandemic: randomised controlled trial

Authors

Hiran Thabrew[1,2], Child and Adolescent Psychiatrist, Paediatrician, Senior Lecturer, h.thabrew@auckland.ac.nz (corresponding author)

Anna Lynette Boggis[1], PhD Student, abog579@aucklanduni.ac.nz

David Lim[1], Masters Student, david_lim@tutunota.com

Kiralee Schache[3], Health Psychologist, kiralee.schache@middlemore.co.nz

Eva Morunga[2], Health Psychologist, emorunga@adhb.govt.nz

Nic Cao[3], Health Psychologist, n.cao@auckland.ac.nz

Alana Cavadino[4], Biostatistician, a.cavadino@auckland.ac.nz

Anna Sofia Serlachius[1], Health Psychologist, Senior Lecturer, a.serlachius@auckland.ac.nz

Affiliations

[1] Department of Psychological Medicine, Faculty of Medical and Health Sciences, The University of Auckland, New Zealand

[2] Auckland District Health Board, Auckland, New Zealand

[3] Counties Manukau District Health Board, Auckland, New Zealand

[4] Department of Epidemiology and Biostatistics, Faculty of Medical and Health Sciences, The University of Auckland, New Zealand

Contact details for corresponding author

Dr Hiran Thabrew, Department of Psychological Medicine, The University of Auckland, Auckland, New Zealand. Email: h.thabrew@auckland.ac.nz. Tel: +64 9 923 3073.

Author contributions

All authors contributed to the design, development and execution of the study. This paper was drafted by HT, AS and AC and reviewed by all other authors prior to submission to the BMJ.

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Data sharing

The deidentified dataset is available on request from the corresponding author: h.thabrew@auckland.ac.nz.

Abstract

Objectives: To evaluate the efficacy and acceptability of 'Whitu: seven ways in seven days', a well-being application (app) for young people.

Design: Prospective randomised controlled trial of Whitu against waitlist control, with 45 participants in each arm.

Participants: 90 New Zealand young people aged 16-30 recruited via a social media advertising campaign.

Setting: Participants' homes.

Interventions: Developed during the COVID-19 pandemic, and refined from a prototype version that was evaluated during a smaller qualitative study, 'Whitu: seven ways in seven days' is a well-being app that, as its name suggests, contains seven modules to help young people (i) recognise and rate emotions, (ii) learn relaxation and mindfulness, (iii) practice self-compassion and (iv) gratitude, (v) connect with others, (vi) care for their physical health and (vii) engage in goal-setting. It can be completed within a week or as desired.

Main outcome measures Primary outcomes were changes in well-being on the World Health Organisation 5-item well-being index (WHO-5) and short Warwick-Edinburgh mental well-being scale (SWEMWBS). Secondary outcomes were changes in depression on the Centre for Epidemiological Studies Depression Scale (CES-D), anxiety on the Generalised Anxiety Disorder seven item scale (GAD-7), self-compassion on the Self Compassion Scale- Short Form (SCS-SF), stress on the 10-item Perceived Stress Scale (PSS-10) , sleep on the single-item Sleep Quality Scale (SQS), and user engagement on the end-user version of the Mobile Application Rating Scale (uMARS) and via qualitative feedback during an online survey. Outcomes were evaluated at baseline, four weeks (primary study endpoint) and three months, and analysed using linear mixed models with group, time and a group-time interaction.

Results: At 4 weeks, participants in the Whitu group experienced significantly higher emotional (Mean difference (md) 13.19 (3.96, 22.42); p=0.005) and mental (md 2.44 (0.27, 4.61); p=0.027) well-being, self-compassion (md 0.56 (0.28, 0.83); p<0.001) and sleep (md 1.13 (0.24, 2.02); p=0.018), and significantly lower stress (md -4.69 (-7.61, -1.76); p=0.002) and depression (md -5.34 (-10.14, -0.53); p=0.030), compared to the waitlist controls. Group differences remained statistically significant at 3 months for all outcomes. Symptoms of anxiety were also lower in the intervention group at 4 weeks (p=0.096), with statistically significant differences at 3 months (md -2.31 (-4.54, -0.08); p=0.042). Usability of Whitu was high (subjective ratings of 4.45 (0.72) and 4.38 (0.79) out of 5 at 4 weeks and 3 months respectively) and qualitative feedback indicated individual and cultural acceptability of the app.

Conclusions: Given the evolving psychological burden of the COVID-19 pandemic, Whitu could provide a clinically effective and scalable means of improving the well-being, mental health and resilience of young people. Replication of current findings with younger individuals and in other settings is planned.

Trial Registration: This study was registered with the Australian New Zealand Clinical Trials Network Registry: ACTRN12620000516987

Keywords:
COVID-19; pandemic; mental health; mobile apps; mHealth; coping skills; well-being; adolescent; young adult

Article Summary

Strengths and limitations of this study

- This randomised controlled trial was conducted with adequate power, a low drop-out rate and a small amount of missing data.
- Key audiences of New Zealand Māori and Pacific young people were included.
- Enrolment was limited to users over 16 years of age and there were fewer male participants.

- Outcome measures were self-reported and there was no blinding of participants or researchers.

Introduction

The 'invisible pandemic' of psychological issues associated with COVID-19 is only beginning to be realised [1,2]. Young people are particularly vulnerable to developing such issues due to pre-existing mental health challenges[3] and lockdown-related disruption of their developmentally-related needs [4]. Within the past year, increased rates of mental distress [5], anxiety [6], depression [7-9] and suicidal ideation [10] have already been identified among young people in multiple countries. Additionally, those who have contracted COVID-19 have reported high rates of post-traumatic stress disorder [11]. Long-term adverse health, academic and occupational consequences of these psychological issues are likely [3,7,12,13], especially in previously recognised subgroups with greater health needs [11,14]. Despite increased demand for psychological support, access to face to face services has been significantly disrupted and delayed[15,16]. Furthermore, evidence-based interventions for preventing and addressing psychological issues related to the pandemic are rare [17].

Over the past decade, an increasing body of research has demonstrated the effectiveness of digital mental health interventions at improving the well-being and mental health of young people [18-20]. This has led to some being recommended as first line treatments for conditions such as depression by the National Institute for Clinical Excellence (NICE) in the UK [21]. Given the frequency of smartphone use by young people [16], mobile health applications (apps) have particular appeal as a means of supporting young people to safely and conveniently learn and practice skills in the real world [15,16,18,19]. However, out of over 20,000 available mobile health apps, very few have evidence of efficacy [22]. Since the onset of the pandemic, the demand for mobile health apps has considerably increased [23] and policy makers have recognised them as a widely disseminable means of improving immediate and longer-term well-being [24].

Prior to the pandemic, New Zealand young people were experiencing high levels of mental distress, depression and the highest suicide rate among developed countries [25-28]. Due to concerns about these issues becoming significantly worse in the context of mandated social distancing and repeated lockdowns, our research team rapidly developed an app to support the emotional well-being of this group, with special emphasis on the needs of young people of Māori and Pacific ethnicity who had always been disproportionately affected by mental health issues [15,16]. 'Whitu: seven ways in seven days' (Whitu meaning seven in the NZ Māori language 'Te Reo') was based on a range of cognitive behavioural therapy (CBT), psychoeducation, and positive psychology techniques previously shown to have efficacy in young people [15,16,18]. The development of Whitu is discussed in more detail in our protocol paper [29]. A small pilot trial (n=20) of the prototype app demonstrated statistically significant within-group improvements in well-being (p=.021), anxiety (p=.005), depression (p=.031) and stress (p=.004) between baseline and 6-weeks, but no significant changes in self-compassion, or sleep (in press, data available from the authors on request). User feedback led to improvements being made to the look and feel, cultural content and onboarding experience. This randomised controlled trial was undertaken to evaluate the efficacy, usability and acceptability of the refined version of the app. We hypothesised that, compared with a wait-list control group, users of Whitu would experience improved well-being, self-compassion, sleep, and reduced stress, anxiety and depression at four weeks and three months. Secondarily, we hypothesised that Whitu would be usable and acceptable to young people.

Methods

Study design

A mixed methods approach was used to determine the efficacy, usability and acceptability of 'Whitu'. The study was prospectively registered with the Australian New Zealand Clinical Trials Registry (ACTRN12620000516987) and received ethics approval from the University of Auckland Human Participant Ethics Committee (Reference 024542).

Participants

New Zealand residents aged between 16 and 30 years who had reliable access to Wi-Fi, owned either an iPhone or Android mobile phone, were considered 'healthy volunteers' and not currently receiving mental health treatment, and could read and understand enough English to use the app via an online social media advertising campaign were recruited for the study. Participants were provided with a NZD $40 (GBP 20) gift voucher on exit from the study as a thank you for their time.

Procedures

To optimise recruitment of New Zealand Māori and Pacific young people, the study was initially promoted to these groups via social media, and later opened up to individuals of any ethnicity. Participants (i) read study information, (ii) completed informed consent procedures and baseline questionnaires, and (iii) were randomised to either the intervention group (Whitu app) or wait-list control group via REDCap®, a secure web application designed to capture data for clinical research and projects that includes a randomisation module. At the point of recruitment, participants were asked not to use any well-being or mental health apps for the duration of the study. At the end of the study, they were also asked if they had done so, but none said that they had. Due to the nature of the study, neither participants nor researchers were blinded to treatment allocation. The intervention group was encouraged to download

and use the app for four weeks. Both groups completed outcome measures via REDCap® at four weeks and three months, following which control group participants were also provided with the app. No outcome measures were collected beyond this point. Further details are provided in our study protocol [29].

Intervention

Whitu: seven ways in seven days is a free mobile application (app) that is currently available to New Zealand users via the App Store (https://apps.apple.com/nz/app/whitu/id1508135602?ign-mpt=uo%3D4) and Google Play Store (https://play.google.com/store/apps/details?id=com.carbonimagineering.whitu). It contains seven positive psychology, CBT and psychoeducation-based modules that can be completed within a week. Users are encouraged to choose from a broad range of strategies and discover the ones that best work for them. Badge rewards and daily notifications encourage app completion and practice of preferred strategies. Further details of the app are provided in Table 1 and Figure 1. No user information or app analytic data are collected or stored over the Internet. Data entered by users are stored on their devices in an unencrypted SQLite database and can be safely removed at any time by deleting the app.

Table 1: The seven modules of Whitu

Module 1: Feel	The first module acknowledges that young people may be feeling low and struggling with negative emotions due to the pandemic. The module introduces the concept of identifying and monitoring emotions, and identifying adaptive and maladaptive coping skills.

Module 2: Relax	The second module addresses the uncertainty and stress that young people may be feeling due to the pandemic. Users are introduced to relaxation techniques such as deep breathing, progressive muscle relaxation, and guided visualization.
Module 3: Be kind to yourself	The third module introduces the concept of self-compassion and users are guided through a short meditation and self-kindness writing exercise.
Module 4: Be thankful	The fourth module introduces the concept of gratitude and how it is linked to positive wellbeing. Users are encouraged to create and use a diary or photographic record of things for which they are grateful.
Module 5: Connect	The fifth module addresses the negative impact that lockdowns and physical distancing can have on relationships. Users are encouraged to identify important people in their lives and practice ways of staying connected with them.
Module 6: Look after your body	The sixth module discusses how the pandemic makes it more difficult to stay active and look after our bodies. Users are encouraged to eat more healthily, identify and use available forms of exercise and practice good sleep hygiene.
Module 7: Set goals	The final module acknowledges that the pandemic has probably interrupted routines and made it harder to set healthy goals. User are introduced SMART goals and encouraged to practice setting and achieving at least one such goal.

Figure 1: Images of Whitu modules, including activities and badges

Outcomes

Demographic data, including sex, age, and ethnicity, were collected from all participants via REDCap® at baseline. Outcome measures were assessed at baseline, four-week and three-month follow-up, with emotional and mental well-being outcomes at 4-weeks being the primary endpoints. Emotional well-being was measured using the 5-item World Health Organisation Well-Being Index (WHO-5) [30]. Mental well-being was measured by the seven-item Short Warwick-Edinburgh Mental Well-being Scale (SWEMWBS) [31,32]. The scale has demonstrated good reliability (α=.84) and validity in adolescent and young adult populations [33,34]. Depression was measured by the 20-item Center for Epidemiological Studies Depression Scale (CES-D) [35]. The CES-D demonstrates high correlations with other depression measures and excellent internal consistency (α=.85) [35]. Anxiety was measured by

the Generalised Anxiety Disorder 7-item Scale (GAD-7) [36]. The scale has demonstrated excellent reliability (α=.92) and validity in adults [37] and adolescents [38]. Self-compassion was measured by the Self-Compassion Scale-Short Form (SCS-SF) [39]. The scale has demonstrated good reliability (α >.86) in an adolescent sample [40]. Stress was measured by the 10-item Perceived Stress Scale (PSS-10) [41,42]. The PSS-10 scale has demonstrated excellent psychometric properties compared to other stress measures, with good reliability and validity [43]. Sleep quality was measured by the single-item Sleep Quality Scale (SQS) [44]. The SQS has been shown to have excellent concurrent and convergent validity with other lengthier sleep scales and has been demonstrated to be effective in determining clinically meaningful changes in sleep quality. User engagement was assessed by the app Subjective Quality subscale and the Perceived Impact subscale of the end-user version of the uMARS measure [45]. The Subjective Quality subscale score consists of four items that determine user experience (e.g., Would you pay for this app?"). The Perceived Impact subscale score is derived from 6 items measuring the impact of using the app on knowledge, attitudes, and intentions. The uMARS demonstrates good internal reliability (α=.90), and the subscales demonstrate moderate reliability (α=.71 and .80) [45]. In addition to the uMARS, participants also answered how many modules of the *Whitu* app they completed at each time point (1-7 modules) and provided brief qualitative feedback about their experience of using the app via an open-ended question in REDCap®.

Data Analysis

Using Gpower [46], we estimated a sample size of 90 participants (45 per treatment arm) would provide an effect size of *f*=0.155 for between group improvement in well-being using the WHO-5 index using a mixed analysis of variance (ANOVA) including within (three time points) and between (two groups) subject effects, with 90% power and at a two-sided

significance level of 5%. This effect size relates to the between-group improvement in well-being found in a previous study of a web-based positive psychology intervention for mildly depressed adults [47]. To ensure cultural acceptability of the app, we planned to recruit at least 36 (40%) young people of Māori and Pacific Island ethnicity. Baseline characteristics were summarized using means and standard deviations or numbers and percentages. Repeated measures ANOVA was used with linear mixed models to include participants missing data at any of the three time points. The primary analysis aimed to determine whether changes in psychological outcomes were the result of the interaction between the intervention group and time, with post-hoc tests to assess pairwise comparisons of groups at each time point and within-group changes over time. Cohens f^2 was calculated as a measure of effect size for the group by time interaction [48]. The primary comparisons of interest were between group differences at 4 weeks and 3 months, with results presented as marginal mean differences, 95% CIs and p-values. Data were analysed on an intention-to-treat basis using Stata® software version 17, and statistical significance was set at $p<0.05$. Qualitative feedback was independently extracted and analysed by two authors (HT and AS) using directed content analysis [49]. Data was examined to the point of thematic saturation and any discrepancies in coding were resolved by consensus.

Patient and Public Involvement

Whitu was actively co-designed with New Zealand young people during the COVID-19 pandemic [29]. However, no patients were involved in setting the research question or in developing plans for recruitment, design, implementation and dissemination of the results of the study.

Results

Participant characteristics

Of the 299 individuals who expressed interest, the first 90 eligible participants who met criteria were recruited to the study (45 per arm) between November 2020 and January 2021. One participant withdrew from the intervention arm without using the app due to technical difficulties or choice, four from the same arm were lost to follow-up at four weeks and another at three months. Only one participant was lost from the control arm at four weeks. Further details are presented in the CONSORT flow diagram (Figure 2).

Figure 2: CONSORT flow diagram

Participants ranged between 16 and 30 years, with a mean age of 23.8 years (SD 3.8). The majority of participants were female (n=79; 87.8%) and were students (n=59; 69.6%). Around a third reported having chronic health conditions including anorexia, anxiety, asthma, bipolar disorder, depression, eczema, epilepsy, hay-fever, hyperthyroidism, insomnia, migraines and polycystic ovarian syndrome. Participant demographics were similar between the intervention and control arm, apart from there being a greater proportion of participants reporting health conditions or medication use in the intervention arm and more participants of Pacific ethnicity in the waitlist arm. Further details are presented in Table 2.

Table 2: Participant demographics

Characteristics	Whitu app (N=45)	Waitlist control (N=45)	Total (N=90)
Age (years); mean (SD)	22.71 (3.67)	24.64 (3.74)	23.68 (3.81)
Gender			
Female	40 (88.9%)	39 (86.7%)	79 (87.8%)
Male	3 (6.7%)	6 (13.3%)	9 (10.0%)
Non-binary	2 (4.4%)	0	2 (2.2%)
Ethnicity *			
New Zealand European	14 (31.1%)	11 (24.4%)	25 (27.8%)
Māori	22 (48.9%)	17 (37.8%)	39 (43.3%)
Pacific	2 (4.4%)	9 (20.0%)	11 (12.2%)
Asian	5 (11.1%)	4 (8.9%)	9 (10.0%)
Other ethnic groups	2 (4.4%)	4 (8.9%)	6 (6.7%)
Occupation			
Paid work	16 (35.6%)	15 (33.3%)	31 (34.4%)
Student	29 (64.4%)	30 (66.7%)	59 (65.6%)
Reported having a health condition	18 (40.0%)	12 (26.7%)	30 (33.3%)
Reported taking medications	14 (31.1%)	6 (13.3%)	20 (22.2%)
Reported previous related app use**	10 (22.2%)	11 (24.4%)	21 (23.3%)

*Data are displayed as N (%), unless otherwise stated. *Pacific including: Samoan (n=6), Tongan (n=4), Fijian/Tuvaluan (n=1); and Asian including: Chinese (n=3), Indian (n=3), NZ Sri-Lankan (n=1), Indonesian (n=1), Taiwanese (n=1); **Apps previously used included Calm (n=7), Headspace (n=13) and Insight (n=1)*

Changes in outcome measures over time

Results presented in Table 3 demonstrate that the intervention had a significant effect, as observed by a significant time by group interaction, on emotional (p=0.04) and mental (p=0.008) well-being, stress (p=0.001) and self-compassion (p=0.003). Measures of well-being and self-compassion were significantly higher and stress was significantly lower in the intervention group at both the 4-week and 3-month follow-up. The interaction between group and time on depression, anxiety and sleep did not reach statistical significance. However, differences between groups indicated evidence of better outcomes for those in the intervention group, with lower levels of depression (significant at both follow-ups) and anxiety (significant at 3-months) and higher sleep scores (significant at both follow-ups) being observed, compared to the waitlist controls. All outcome measures significantly improved over time within the intervention group ($p<0.05$; supplementary Table 1). There were no significant differences in outcome measures over time in the waitlist control group, except for sleep scores, which were higher at both follow-ups compared to baselines, although the effects were smaller compared to the intervention group (supplementary Table 1). Further details are presented in Table 3, Figure 3 and Supplementary Table 1.

Table 3: Comparisons between groups in outcome measures over the study period

Outcome	Whitu app (N=45) Mean (SD)	Waitlist control (N=45) Mean (SD)	Marginal mean difference Whitu vs control (95% CI)	*P value*	*Group by time interaction P value*	*Cohen's f^2 effect Size*
Emotional well-being (WHO-5)						
Baseline	50.13 (20.42)	46.84 (23.78)	3.29 (-5.69, 12.27)	0.473		
4 weeks	55.28 (23.03)	42.13 (21.02)	13.19 (3.96, 22.42)	**0.005**	**0.043**	*$f^2 = 0.050$*
3 months	60.51 (18.70)	47.09 (22.74)	13.77 (4.50, 23.03)	**0.004**		
Mental well-being (SWEMBS)						
Baseline	22.36 (5.06)	22.24 (5.16)	0.11 (-2.00, 2.23)	0.918		
4 weeks	24.69 (4.98)	22.27 (5.04)	2.44 (0.27, 4.61)	**0.027**	**0.008**	*$f^2 = 0.077$*
3 months	24.58 (4.95)	21.70 (5.47)	3.01 (0.82, 5.20)	**0.007**		
Depression (CES-D)						
Baseline	20.71 (12.56)	22.31 (11.51)	-1.60 (-6.30, 3.10)	0.504		
4 weeks	15.72 (10.15)	21.56 (11.54)	-5.34 (-10.14, -0.53)	**0.030**	0.061	*$f^2 = 0.049$*
3 months	16.26 (9.42)	23.07 (12.15)	-6.62 (-11.43, -1.82)	**0.007**		
Anxiety (GAD-7)						
Baseline	9.38 (5.87)	9.42 (5.36)	-0.04 (-2.21, 2.12)	0.968		
4 weeks	6.54 (4.76)	8.56 (5.74)	-1.89 (-4.11, 0.33)	0.096	0.060	*$f^2 = 0.047$*
3 months	6.05 (4.22)	8.48 (5.15)	-2.31 (-4.54, -0.08)	**0.042**		
Stress (PSS-10)						
Baseline	21.84 (7.08)	21.62 (7.07)	0.22 (-2.63, 3.07)	0.878	**0.001**	*$f^2 = 0.108$*
4 weeks	16.62 (6.34)	21.42 (7.24)	-4.69 (-7.61, -1.76)	**0.002**		

3 months	17.33 (6.32)	21.41 (7.29)	-3.85 (-6.77, -0.91)	**0.010**		
Self-compassion (SCS-SF)						
Baseline	2.77 (0.68)	2.69 (0.60)	0.08 (-0.19, 0.35)	0.554		
4 weeks	3.21 (0.55)	2.68 (0.66)	0.56 (0.28, 0.83)	**<0.001**	**0.003**	$f^2 = 0.094$
3 months	3.11 (0.73)	2.82 (0.66)	0.31 (0.03, 0.59)	**0.028**		
Sleep (SQS)						
Baseline	5.20 (2.05)	4.84 (2.17)	0.36 (-0.51, 1.23)	0.423		
4 weeks	6.90 (1.93)	5.82 (2.23)	1.13 (0.24, 2.02)	**0.013**	0.141	$f^2 = 0.084$
3 months	7.05 (1.85)	6.14 (2.31)	0.92 (0.03, 1.82)	**0.043**		

Figure 3: Marginal mean outcomes by group and study time point

[INSERT FIGURE HERE]

User feedback

Overall, feedback regarding the app was positive, with special mention made by Māori young people regarding features designed to increase cultural appeal such as the introductory 'karanga' (welcome song). Participants expressed diverse, and non-culturally related preferences regarding individual modules, with newly learnt content being most valued. Suggestions for improvement included the use of shorter videos, improved navigation and greater flexibility with reminders (currently set at once per day). Six users with older mobile phones experienced some technical difficulties, but were still able to use the app. Key themes and examples of participant feedback are provided in Table 4. Usability scores for Whitu are also provided in Table 5.

Table 4: Participant feedback

Theme	Examples
Most useful modules or features	"I found the relax one most helpful. I just really enjoy the guided meditation aspect, the main thing that draws me to these apps. Lovely app, will definitely use again" (Participant 346) "I found the 'be thankful' module the most helpful. I liked this one as it made me stop and consciously focus on the positive aspects of my life" (Participant 327) "This is a well-thought out app and will go on to help many individuals like myself. I feel like i should make a special mention of the karanga at the beginning of the app when i first opened and downloaded it. As a young Māori woman, being called into the app and have it welcome all my problems and grief instantly sparked a spiritual connection for me and i instantly felt at ease and felt safe enough to embark on my healing and wellbeing journey. I also enjoyed the constant use of Te Reo Māori and the progress of watching my Puriri tree grow throughout the 4 weeks. It was a pleasant surprise and so culturally inclusive. The voice overs were pleasant to listen to, the videos, sounds and effects captivating. The

	best app after what was such a rollercoaster year! Thank you!" (Participant 376)
Suggestions for improvement	"Make the videos shorter somehow, I think young people nowadays have short attention spans... including me" (Participant 308) "I did find it was sometimes tricky to find the follow up activities I was supposed to do - these could be better signposted/reminders could link to them directly" (Participant 354) "The daily reminder is good, but often came at a time when I was busy! Maybe a second reminder or setup as part of a daily routine" (Participant 333)
Technical difficulties	"On old phone, when completing modules there was graphical glitching (buttons and images being in the wrong place, the background video overlay being stuck in place between menus).There was also some issues with the video. Sometimes it just wouldn't play until I restarted the app" (Participant 335) "Now that I check the app it has logged my progress with Module 2 but I did not find that right after I had completed it" (Participant 337)

Table 5: Usability for n=38 participants in the intervention group using the Whitu app*

Measures	4 weeks (N=38**)	3 months (N=37**)
uMARS (score range 1-5)		
Subjective app quality score	4.45 (0.72)	4.38 (0.79)
Perceived impact: Awareness	3.89 (0.95)	4.00 (1.03)
Perceived impact: Knowledge/understanding	3.76 (1.15)	3.86 (1.03)
Perceived impact: Attitudes	3.58 (1.13)	3.46 (1.28)
Perceived impact: Intention to change	3.71 (1.09)	3.57 (1.34)
Perceived impact: Help seeking	3.66 (1.07)	3.57 (1.07)
Perceived impact: Behavior change	3.63 (1.10)	3.76 (1.19)

Discussion

Overall Findings

To our knowledge, this is the first randomised controlled trial of a well-being app for young people undertaken during the COVID-19 pandemic and it addresses the clear gap in the COVID-related literature (i.e. the lack of studies to address anticipated psychological effects of the pandemic) highlighted by Gilbody et al [50]. Our results indicate that Whitu is an effective, usable and acceptable composite digital health intervention with which to improve multiple aspects of young people's health including well-being, self-compassion, and sleep, and to reduce anxiety, depression and stress. Benefits were evident at four weeks and sustained at three-month follow-up. The fact that well-being in the intervention group actually improved during a pandemic is also clinically significant. Based on uMARS scores (Table 4), usability of Whitu was high, and greater than that of recently developed mental health apps and established norms [51,52].

Comparison with Previous Research

Our findings are consistent with recent review evidence that mindfulness and multi-component interventions are most effective at improving the well-being of clinical and non-clinical populations [53]. Despite the potential floor effect with a non-clinical population, users of Whitu reported significantly improved symptoms of anxiety and depression. Resulting effect sizes were similar to the small to moderate effect sizes of individually-targeted digital interventions for treating these conditions [54], suggesting that Whitu may be beneficial for clinical populations. Since the onset of the pandemic, a rapid review of existing digital mental health interventions has ascertained they are usable, safe, acceptable and likely to be effective in ameliorating at least some of the psychological consequences of lockdown [54]. However, only one other RCT of a four-week mindfulness-based intervention delivered to

Chinese university students via Zoom® and asynchronous WeChat video and audio recordings has actually been undertaken and shown to improve symptoms of anxiety and depression compared with technology-based social support [55].

Given reports that only 3.9% of individuals who download health apps use them for a median of 15 days more than two weeks [56] and that only 0.5 to 28.7% actually complete them [57], the relatively high efficacy and acceptability of Whitu may be related to its intentionally time-limited design. Encouraging young people to learn new self-management strategies via the app and then practice them in the real world should also help with generalisation of these skills [57]. Although some may argue that an app designed to support young people during the pandemic may be of limited chronological relevance, previous evidence from earthquake survivors in New Zealand suggests that psychological effects of major events are likely to be delayed, with rates of problems increasing by between 25-40% even after two year [58,59]. Given the protracted nature of the current pandemic, its true psychological cost will only be obvious in retrospect.

Strengths and Limitations

Strengths of this study include the adequate power, overall low drop-out rate (less than the typical drop-out rate of 25% during studies of other mobile health interventions) [60] and small amount of missing data. In addition, given our desire to develop a culturally safe and relevant app, the appeal of Whitu to Māori and Pacific young people and its efficacy with these groups is reassuring and likely to reduce existing health inequities, thereby honouring New Zealand's commitment to the Treaty of Waitangi [61,62]. Weaknesses of the study include the lack of blinding of participants, inclusion of fewer male participants and use of self-reported outcome measures. It is also possible that group differences may have been smaller if an

active control had been used instead of a waitlist control. As Whitu was designed to preserve well-being in the general population (rather than treat existing mental health issues) and in order to limit confounding from concurrent psychological therapies, inclusion in the study was limited to individuals not currently receiving mental health treatment. As such, its applicability to those already experiencing mental health issues remains unproven and further research with this group would be worthwhile. Around a third of participants reported having an existing health condition and this is in keeping with previous evidence that around 18% of New Zealand high school students and up to 45% of adults live with chronic health conditions [63, 64]. Although it is possible that individuals with pre-existing health issues were more likely to enrol in a study involving the use a new health app, the studied population appears to be representative of young people in the community. A greater proportion of participants dropped out from the intervention group than the control group. Although none of these individuals who dropped out provided feedback on their experience at the end of the study, this difference may reflect challenges in using, or lack of appeal of, eHealth interventions for some young people. Our results need to be replicated in other settings (such as schools) and with young people below 16 years of age to ensure their generalisability. Evaluation of Whitu's efficacy with higher-risk groups such as young people with long-term physical conditions [16] and more objective measures of app use and clinical outcomes would be valuable. Finally, future research would benefit from formal economic analysis to bridge the gap between researcher interests and policymakers [65].

Conclusions

For the moment, this study provides preliminary evidence that Whitu is a clinically effective and scalable means of improving the well-being and mental health of young people during the COVID-19 pandemic.

Contributorship statement

HT and ASS conceived the research question. HT, ASS, ALB, DL, KS, EM, NC and AC designed the study. AC performed sample size calculations. HT and ASS applied for ethics approval and registration of the study. ALB, DL, KS, EM and NC undertook participant recruitment. ALB and DL set up and executed REDCap data collection. ASS, ALB and AC analysed quantitative data. HT and DL analysed qualitative data. EM and NC provided cultural oversight during the study. HT wrote the initial version of this manuscript and ASS, ALB, DL, KS, EM, NC and AC contributed to critical edits. All authors approved the final version of the manuscript. The corresponding author (HT) acts as the guarantor, accepts full responsibility for the work, and attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

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Competing interest statement

No competing interest.

Data sharing statement

Deidentified, collated data from this study are presented in this paper. Individual data sets are not available for sharing as participants did not provide consent for this information to be shared. Any other details of the study procedure are available from the lead author on request (please email h.thabrew@auckland.ac.nz).

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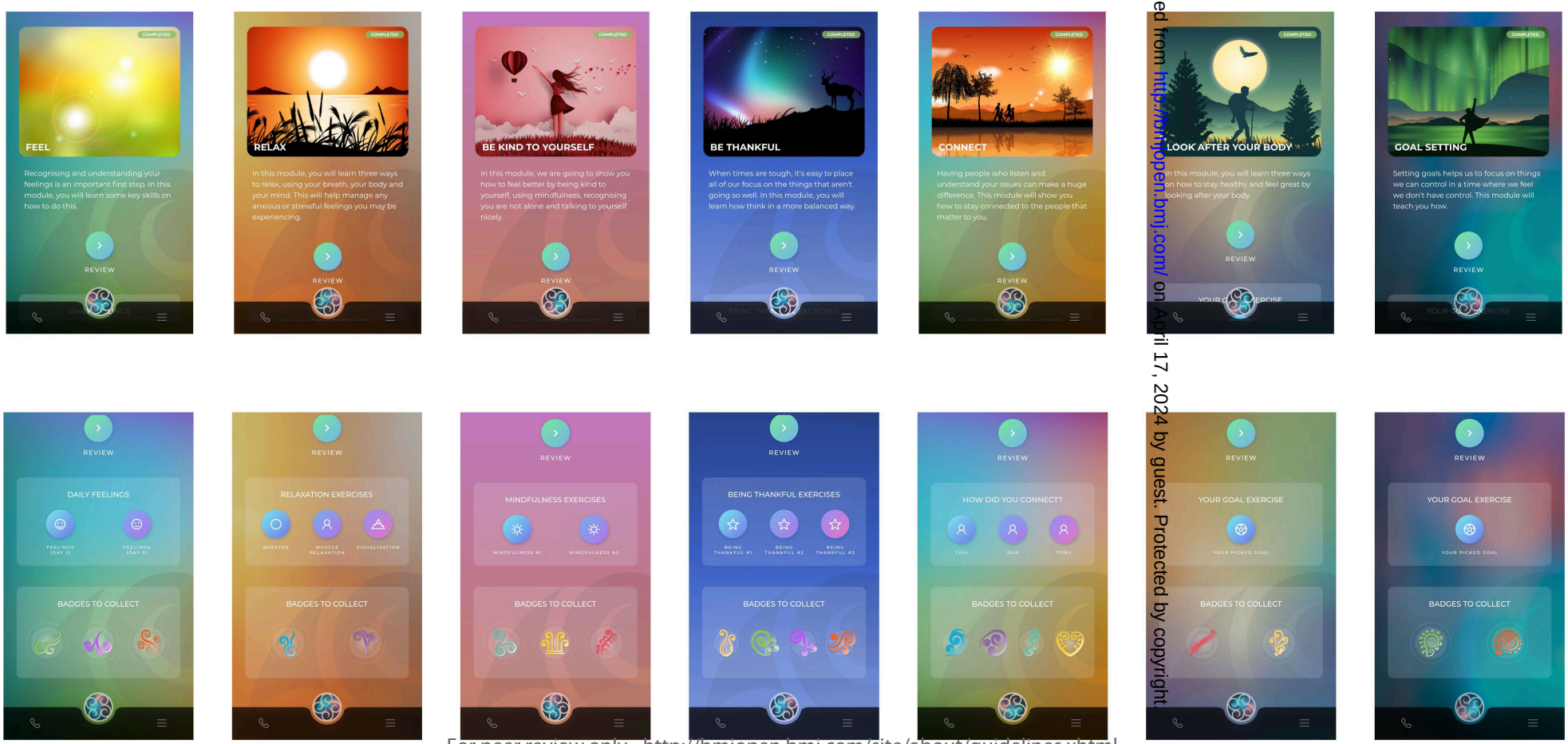

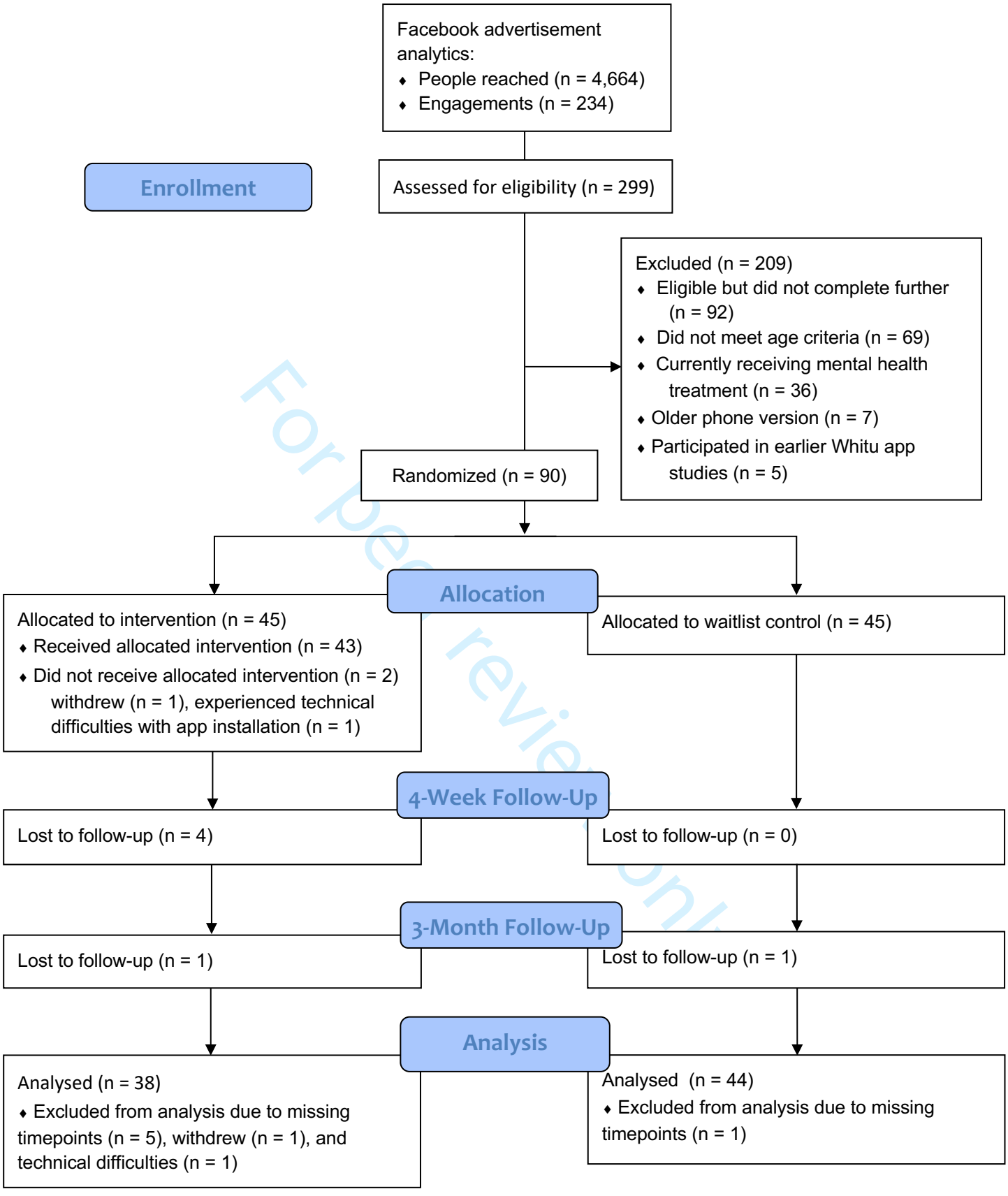

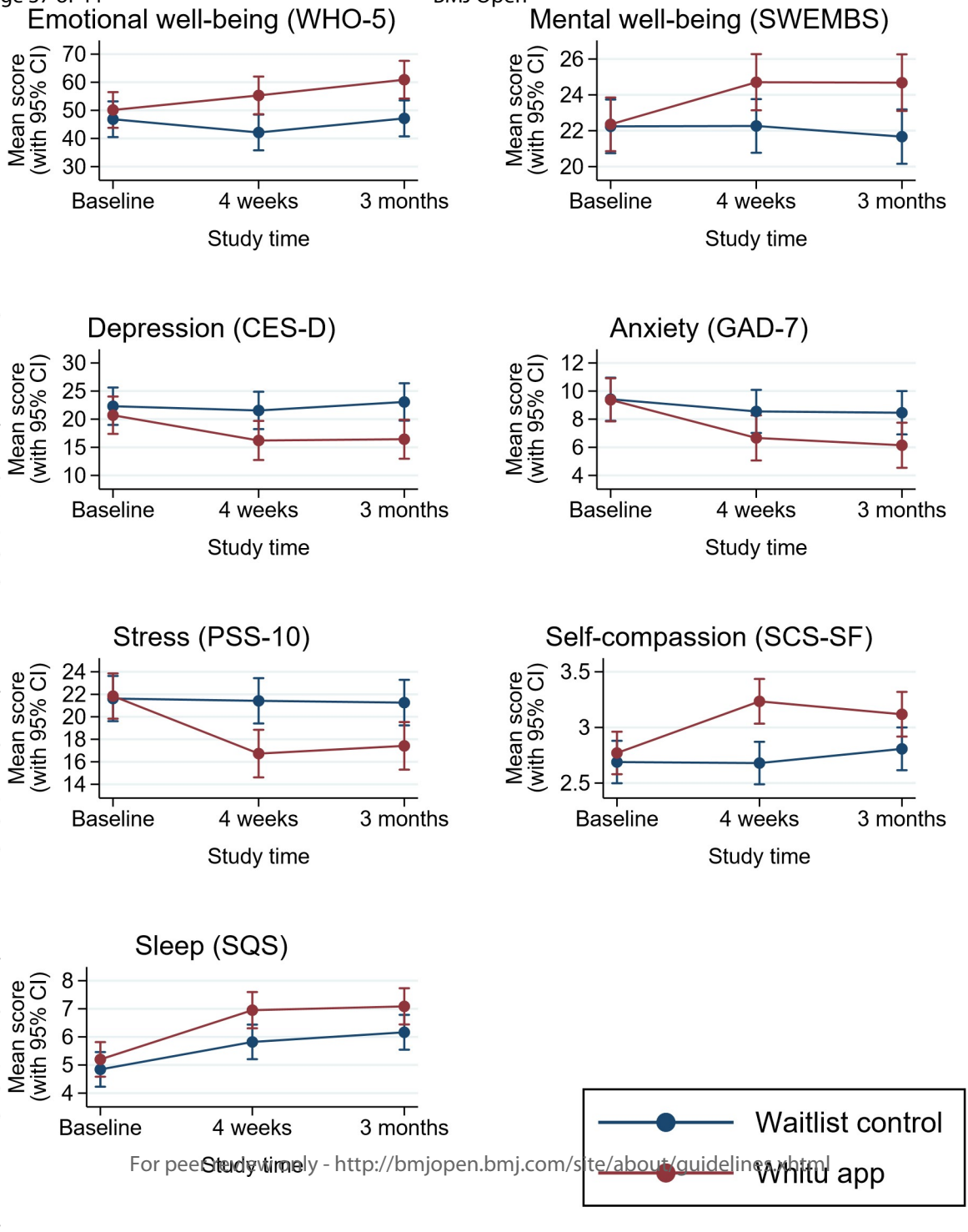

Supplementary table 1: Within group changes in outcome measures over time

Outcome	Whitu app (N=45)			Waitlist control (N=45)			*Group by time Interaction P value*
	Mean (SD)	Mean difference (95% CI)	*P value*	Mean (SD)	Mean difference (95% CI)	*P value*	
Emotional well-being (WHO-5)							
Baseline	50.13 (20.42)	Ref	Ref	46.84 (23.78)	Ref	Ref	
4 weeks	55.28 (23.03)	5.19 (-1.51, 11.89)	0.129	42.13 (21.02)	-4.71 (-11.06, 1.64)	0.146	**0.043**
3 months	60.51 (18.70)	10.78 (4.08, 17.48)	**0.0002**	47.09 (22.74)	0.30 (-6.10, 6.70)	0.927	
Mental well-being (SWEMBS)							
Baseline	22.36 (5.06)	Ref	Ref	22.24 (5.16)	Ref	Ref	
4 weeks	24.69 (4.98)	2.35 (0.95, 3.76)	**0.001**	22.27 (5.04)	0.02 (-1.30, 1.35)	0.974	**0.008**
3 months	24.58 (4.95)	2.33 (0.91, 3.74)	**0.001**	21.70 (5.47)	-0.57 (-1.92, 0.77)	0.404	
Depression (CES-D)							
Baseline	20.71 (12.56)	Ref	Ref	22.31 (11.51)	Ref	Ref	
4 weeks	15.72 (10.15)	-4.29 (-7.64, -1.34)	**0.005**	21.56 (11.54)	-0.76 (-3.73, 2.22)	0.619	0.061
3 months	16.26 (9.42)	-4.27 (-7.42, -1.12)	**0.008**	23.07 (12.15)	0.76 (-2.22, 3.73)	0.619	
Anxiety (GAD-7)							
Baseline	9.38 (5.87)	Ref	Ref	9.42 (5.36)	Ref	Ref	0.060
4 weeks	6.54 (4.76)	-2.71 (-4.16, -1.26)	**<0.001**	8.56 (5.74)	-0.87 (-2.23, 0.50)	0.215	
3 months	6.05 (4.22)	-3.23 (-4.68, -1.78)	**<0.001**	8.48 (5.15)	-0.96 (-2.34, 0.42)	0.172	
Stress (PSS-10)							
Baseline	21.84 (7.08)	Ref	Ref	21.62 (7.07)	Ref	Ref	
4 weeks	16.62 (6.34)	-5.11 (-7.14, -3.09)	**<0.001**	21.42 (7.24)	-0.20 (-2.11, 1.71)	0.838	**0.001**
3 months	17.33 (6.32)	-4.43 (-6.45, -2.40)	**<0.001**	21.41 (7.29)	-0.36 (-2.29, 1.57)	0.716	

Self-compassion (SCS-SF)							
Baseline	2.77 (0.68)	Ref	Ref	2.69 (0.60)	Ref	Ref	
4 weeks	3.21 (0.55)	0.46 (0.27, 0.66)	**<0.001**	2.68 (0.66)	-0.01 (-0.20, 0.18)	0.922	**0.003**
3 months	3.11 (0.73)	0.35 (0.15, 0.55)	**0.001**	2.82 (0.66)	0.12 (-0.07, 0.31)	0.216	
Sleep (SQS)							
Baseline	5.20 (2.05)	Ref	Ref	4.84 (2.17)	Ref	Ref	
4 weeks	6.90 (1.93)	1.75 (1.17, 2.33)	**<0.001**	5.82 (2.23)	0.98 (0.43, 1.52)	**<0.001**	0.141
3 months	7.05 (1.85)	1.89 (1.31, 2.46)	**<0.001**	6.14 (2.31)	1.32 (0.77, 1.87)	**<0.001**	

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	1
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	5
	2b	Specific objectives or hypotheses	6
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	7
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	7
	4b	Settings and locations where the data were collected	7
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	8
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	9
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	10
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	7
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	7
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	7
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	7
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	7

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	N/A
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	10
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	11
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	12
	13b	For each group, losses and exclusions after randomisation, together with reasons	12
Recruitment	14a	Dates defining the periods of recruitment and follow-up	12
	14b	Why the trial ended or was stopped	N/A
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	13
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	14
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	15
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	15
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	16-17
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	14
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	19
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	19
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	19
Other information			
Registration	23	Registration number and name of trial registry	4
Protocol	24	Where the full trial protocol can be accessed, if available	4
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	20

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

TIDieR Template for Intervention Description and Replication

The TIDieR (Template for Intervention Description and Replication) Checklist*:

Information to include when describing an intervention and the location of the information

Item number	Item	Where located **	
		Primary paper (page or appendix number)	Other † (details)
	BRIEF NAME		
1.	Provide the name or a phrase that describes the intervention. **A well-being app to support young people during the COVID-19 pandemic**	1	
	WHAT		
2.	Describe any rationale, theory, or goal of the elements essential to the intervention. **A well-being app that, as its name suggests, contains seven positive psychology, CBT and psychoeducation-based modules to help young people (i) recognise and rate emotions, (ii) learn relaxation and mindfulness, (iii) practice self-compassion and (iv) gratitude, (v) connect with others, (vi) care for their physical health and (vii) engage in goal-setting. It can be completed within a week or as desired.**	6	
3.	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL). **Whitu: seven ways in seven days is a free-to-user mobile application (app) that is available on the App Store (https://apps.apple.com/nz/app/whitu/id1508135602?ign-mpt=uo%3D4) and Google Play Store (https://play.google.com/store/apps/details?id=com.carbonimagineering.whitu) for New Zealand residents.**	8	
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities. **Prospective randomised controlled trial of Whitu against waitlist control, with 45 participants in each arm. 90 New Zealand young people aged 16-30 recruited via a social media advertising**	6	

	campaign. Primary outcomes were changes in well-being on the World Health Organisation 5-item well-being index (WHO-5) and short Warwick-Edinburgh mental well-being scale (SWEMWBS). Secondary outcomes were changes in depression on the Centre for Epidemiological Studies Depression Scale (CES-D), anxiety on the Generalised Anxiety Disorder seven item scale (GAD-7), self-compassion on the Self Compassion Scale- Short Form (SCS-SF), stress on the 10-item Perceived Stress Scale (PSS-10) ,sleep on the single-item Sleep Quality Scale (SQS) and user engagement on the end-user version of the Mobile Application Rating Scale (uMARS) and via qualitative feedback. Outcomes were evaluated at baseline, four weeks (primary study endpoint) and three months, and analysed using linear mixed models with group, time and a group-time interaction.		
	WHO PROVIDED		
5.	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given. **N/A (self-help intervention (app) utilised without therapeutic support)**		
	HOW		
6.	Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group. **App downloaded onto participants' mobile phones and individually used.**	7_	
	WHERE		
7.	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features. **Intervention completed in participants' homes**.	7_	
	WHEN and HOW MUCH		
8.	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	7_	

	App designed to be flexibly used, but ideally completed within a week. Users given up to 4 weeks to complete the intervention.		
	TAILORING		
9.	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how. **Users could complete most modules in any order that they wished and repeat preferred exercises as often as desired.**	7	
	MODIFICATIONS		
10.‡	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how). **N/A**		
	HOW WELL		
11.	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them. **N/A (as the intervention was designed to be flexibly used, this was not relevant)**		
12.‡	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned. **N/A**		

** **Authors** - use N/A if an item is not applicable for the intervention being described. **Reviewers** – use '?' if information about the element is not reported/not sufficiently reported.

† If the information is not provided in the primary paper, give details of where this information is available. This may include locations such as a published protocol or other published papers (provide citation details) or a website (provide the URL).

‡ If completing the TIDieR checklist for a protocol, these items are not relevant to the protocol and cannot be described until the study is complete.

* We strongly recommend using this checklist in conjunction with the TIDieR guide (see *BMJ* 2014;348:g1687) which contains an explanation and elaboration for each item.

* The focus of TIDieR is on reporting details of the intervention elements (and where relevant, comparison elements) of a study. Other elements and methodological features of studies are covered by other reporting statements and checklists and have not been duplicated as part of the TIDieR checklist. When a **randomised trial** is being reported, the TIDieR checklist should be used in conjunction with the CONSORT statement (see www.consort-statement.org) as an extension of **Item 5 of the CONSORT 2010 Statement.** When a **clinical trial protocol** is being reported, the TIDieR checklist should be used in conjunction with the SPIRIT statement as an extension of **Item 11 of the SPIRIT 2013 Statement** (see www.spirit-statement.org). For alternate study designs, TIDieR can be used in conjunction with the appropriate checklist for that study design (see www.equator-network.org).

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A well-being app to support young people during the COVID-19 pandemic:randomised controlled trial

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A well-being app to support young people during the COVID-19 pandemic: randomised controlled trial

Authors

Hiran Thabrew[1,2], Child and Adolescent Psychiatrist, Paediatrician, Senior Lecturer, h.thabrew@auckland.ac.nz (corresponding author)

Anna Lynette Boggis[1], PhD Student, abog579@aucklanduni.ac.nz

David Lim[1], Masters Student, david_lim@tutunota.com

Kiralee Schache[3], Health Psychologist, kiralee.schache@middlemore.co.nz

Eva Morunga[2], Health Psychologist, emorunga@adhb.govt.nz

Nic Cao[3], Health Psychologist, n.cao@auckland.ac.nz

Alana Cavadino[4], Biostatistician, a.cavadino@auckland.ac.nz

Anna Sofia Serlachius[1], Health Psychologist, Senior Lecturer, a.serlachius@auckland.ac.nz

Affiliations

[1] Department of Psychological Medicine, Faculty of Medical and Health Sciences, The University of Auckland, New Zealand

[2] Auckland District Health Board, Auckland, New Zealand

[3] Counties Manukau District Health Board, Auckland, New Zealand

[4] Department of Epidemiology and Biostatistics, Faculty of Medical and Health Sciences, The University of Auckland, New Zealand

Contact details for corresponding author

Dr Hiran Thabrew, Department of Psychological Medicine, The University of Auckland, Auckland, New Zealand. Email: h.thabrew@auckland.ac.nz. Tel: +64 9 923 3073.

Author contributions

All authors contributed to the design, development and execution of the study. This paper was drafted by HT, AS and AC and reviewed by all other authors prior to submission to the BMJ.

License for publication

Data sharing

Deidentified, collated data from this study are presented in this paper. Individual data sets are not available for sharing as participants did not provide consent for this information to be shared. Any other details of the study procedure are available from the lead author on request (please email h.thabrew@auckland.ac.nz).

Abstract

Objectives: To evaluate the efficacy and acceptability of 'Whitu: seven ways in seven days', a well-being application (app) for young people.

Design: Prospective randomised controlled trial of Whitu against waitlist control, with 45 participants in each arm.

Participants: 90 New Zealand young people aged 16-30 recruited via a social media advertising campaign.

Setting: Participants' homes.

Interventions: Developed during the COVID-19 pandemic, and refined from a prototype version that was evaluated during a smaller qualitative study, 'Whitu: seven ways in seven days' is a well-being app that, as its name suggests, contains seven modules to help young people (i) recognise and rate emotions, (ii) learn relaxation and mindfulness, (iii) practice self-compassion and (iv) gratitude, (v) connect with others, (vi) care for their physical health and (vii) engage in goal-setting. It can be completed within a week or as desired.

Main outcome measures Primary outcomes were changes in well-being on the World Health Organisation 5-item well-being index (WHO-5) and short Warwick-Edinburgh mental well-being scale (SWEMWBS). Secondary outcomes were changes in depression on the Centre for Epidemiological Studies Depression Scale (CES-D), anxiety on the Generalised Anxiety Disorder seven item scale (GAD-7), self-compassion on the Self Compassion Scale- Short Form (SCS-SF), stress on the 10-item Perceived Stress Scale (PSS-10) , sleep on the single-item Sleep Quality Scale (SQS), and user engagement on the end-user version of the Mobile Application Rating Scale (uMARS) and via qualitative feedback during an online survey. Outcomes were evaluated at baseline, four weeks (primary study endpoint) and three months, and analysed using linear mixed models with group, time and a group-time interaction.

Results: At 4 weeks, participants in the Whitu group experienced significantly higher emotional (Mean difference (md) 13.19 (3.96, 22.42); p=0.005) and mental (md 2.44 (0.27, 4.61); p=0.027) well-being, self-compassion (md 0.56 (0.28, 0.83); p<0.001) and sleep (md 1.13 (0.24, 2.02); p=0.018), and significantly lower stress (md -4.69 (-7.61, -1.76); p=0.002) and depression (md -5.34 (-10.14, -0.53); p=0.030), compared to the waitlist controls. Group differences remained statistically significant at 3 months for all outcomes. Symptoms of anxiety were also lower in the intervention group at 4 weeks (p=0.096), with statistically significant differences at 3 months (md -2.31 (-4.54, -0.08); p=0.042). Usability of Whitu was high (subjective ratings of 4.45 (0.72) and 4.38 (0.79) out of 5 at 4 weeks and 3 months respectively) and qualitative feedback indicated individual and cultural acceptability of the app.

Conclusions: Given the evolving psychological burden of the COVID-19 pandemic, Whitu could provide a clinically effective and scalable means of improving the well-being, mental health and resilience of young people. Replication of current findings with younger individuals and in other settings is planned.

Trial Registration: This study was registered with the Australian New Zealand Clinical Trials Network Registry: ACTRN12620000516987

Keywords:
COVID-19; pandemic; mental health; mobile apps; mHealth; coping skills; well-being; adolescent; young adult

Article Summary

Strengths and limitations of this study

- This randomised controlled trial was conducted with adequate power, a low drop-out rate and a small amount of missing data.
- Key audiences of New Zealand Māori and Pacific young people were included.
- Enrolment was limited to users over 16 years of age and there were fewer male participants.

- Outcome measures were self-reported and there was no blinding of participants or researchers.

Introduction

The 'invisible pandemic' of psychological issues associated with COVID-19 is only beginning to be realised [1,2]. Young people are particularly vulnerable to developing such issues due to pre-existing mental health challenges[3] and lockdown-related disruption of their developmentally-related needs [4]. Within the past year, increased rates of mental distress [5], anxiety [6], depression [7-9] and suicidal ideation [10] have already been identified among young people in multiple countries. Additionally, those who have contracted COVID-19 have reported high rates of post-traumatic stress disorder [11]. Long-term adverse health, academic and occupational consequences of these psychological issues are likely [3,7,12,13], especially in previously recognised subgroups with greater health needs [11,14]. Despite increased demand for psychological support, access to face to face services has been significantly disrupted and delayed[15,16]. Furthermore, evidence-based interventions for preventing and addressing psychological issues related to the pandemic are rare [17].

Over the past decade, an increasing body of research has demonstrated the effectiveness of digital mental health interventions at improving the well-being and mental health of young people [18-20]. This has led to some being recommended as first line treatments for conditions such as depression by the National Institute for Clinical Excellence (NICE) in the UK [21]. Given the frequency of smartphone use by young people [16], mobile health applications (apps) have particular appeal as a means of supporting young people to safely and conveniently learn and practice skills in the real world [15,16,18,19]. However, out of over 20,000 available mobile health apps, very few have evidence of efficacy [22]. Since the onset of the pandemic, the demand for mobile health apps has considerably increased [23] and policy makers have recognised them as a widely disseminable means of improving immediate and longer-term well-being [24].

Prior to the pandemic, New Zealand young people were experiencing high levels of mental distress, depression and the highest suicide rate among developed countries [25-28]. Due to concerns about these issues becoming significantly worse in the context of mandated social distancing and repeated lockdowns, our research team rapidly developed an app to support the emotional well-being of this group, with special emphasis on the needs of young people of Māori and Pacific ethnicity who had always been disproportionately affected by mental health issues [15,16]. 'Whitu: seven ways in seven days' (Whitu meaning seven in the NZ Māori language 'Te Reo') was based on a range of cognitive behavioural therapy (CBT), psychoeducation, and positive psychology techniques previously shown to have efficacy in young people [15,16,18]. The development of Whitu is discussed in more detail in our protocol paper [29]. A small pilot trial (n=20) of the prototype app demonstrated statistically significant within-group improvements in well-being (p=.021), anxiety (p=.005), depression (p=.031) and stress (p=.004) between baseline and 6-weeks, but no significant changes in self-compassion, or sleep (in press, data available from the authors on request). User feedback led to improvements being made to the look and feel, cultural content and onboarding experience. This randomised controlled trial was undertaken to evaluate the efficacy, usability and acceptability of the refined version of the app. We hypothesised that, compared with a wait-list control group, users of Whitu would experience improved well-being, self-compassion, sleep, and reduced stress, anxiety and depression at four weeks and three months. Secondarily, we hypothesised that Whitu would be usable and acceptable to young people.

Methods

Study design

A mixed methods approach was used to determine the efficacy, usability and acceptability of 'Whitu'. The study was prospectively registered with the Australian New Zealand Clinical Trials Registry (ACTRN12620000516987) and received ethics approval from the University of Auckland Human Participant Ethics Committee (Reference 024542).

Participants

New Zealand residents aged between 16 and 30 years who had reliable access to Wi-Fi, owned either an iPhone or Android mobile phone, were considered 'healthy volunteers' and not currently receiving mental health treatment, and could read and understand enough English to use the app via an online social media advertising campaign were recruited for the study. Participants were provided with a NZD $40 (GBP 20) gift voucher on exit from the study as a thank you for their time.

Procedures

To optimise recruitment of New Zealand Māori and Pacific young people, the study was initially promoted to these groups via social media, and later opened up to individuals of any ethnicity. Participants (i) read study information, (ii) completed informed consent procedures and baseline questionnaires, and (iii) were randomised to either the intervention group (Whitu app) or wait-list control group via REDCap®, a secure web application designed to capture data for clinical research and projects that includes a randomisation module. At the point of recruitment, participants were asked not to use any well-being or mental health apps for the duration of the study. At the end of the study, they were also asked if they had done so, but none said that they had. Due to the nature of the study, neither participants nor researchers were blinded to treatment allocation. The intervention group was encouraged to download

and use the app for four weeks. Both groups completed outcome measures via REDCap® at four weeks and three months, following which control group participants were also provided with the app. No outcome measures were collected beyond this point. Further details are provided in our study protocol [29].

Intervention

Whitu: seven ways in seven days is a free mobile application (app) that is currently available to New Zealand users via the App Store (https://apps.apple.com/nz/app/whitu/id1508135602?ign-mpt=uo%3D4) and Google Play Store (https://play.google.com/store/apps/details?id=com.carbonimagineering.whitu). It contains seven positive psychology, CBT and psychoeducation-based modules that can be completed within a week. Users are encouraged to choose from a broad range of strategies and discover the ones that best work for them. Badge rewards and daily notifications encourage app completion and practice of preferred strategies. Further details of the app are provided in Table 1 and Figure 1. No user information or app analytic data are collected or stored over the Internet. Data entered by users are stored on their devices in an unencrypted SQLite database and can be safely removed at any time by deleting the app.

Table 1: The seven modules of Whitu

Module 1: Feel	The first module acknowledges that young people may be feeling low and struggling with negative emotions due to the pandemic. The module introduces the concept of identifying and monitoring emotions, and identifying adaptive and maladaptive coping skills.

Module 2: Relax	The second module addresses the uncertainty and stress that young people may be feeling due to the pandemic. Users are introduced to relaxation techniques such as deep breathing, progressive muscle relaxation, and guided visualization.
Module 3: Be kind to yourself	The third module introduces the concept of self-compassion and users are guided through a short meditation and self-kindness writing exercise.
Module 4: Be thankful	The fourth module introduces the concept of gratitude and how it is linked to positive wellbeing. Users are encouraged to create and use a diary or photographic record of things for which they are grateful.
Module 5: Connect	The fifth module addresses the negative impact that lockdowns and physical distancing can have on relationships. Users are encouraged to identify important people in their lives and practice ways of staying connected with them.
Module 6: Look after your body	The sixth module discusses how the pandemic makes it more difficult to stay active and look after our bodies. Users are encouraged to eat more healthily, identify and use available forms of exercise and practice good sleep hygiene.
Module 7: Set goals	The final module acknowledges that the pandemic has probably interrupted routines and made it harder to set healthy goals. User are introduced SMART goals and encouraged to practice setting and achieving at least one such goal.

Figure 1: Images of Whitu modules, including activities and badges

Outcomes

Demographic data, including sex, age, and ethnicity, were collected from all participants via REDCap® at baseline. Outcome measures were assessed at baseline, four-week and three-month follow-up, with emotional and mental well-being outcomes at 4-weeks being the primary endpoints. Emotional well-being was measured using the 5-item World Health Organisation Well-Being Index (WHO-5) [30]. Mental well-being was measured by the seven-item Short Warwick-Edinburgh Mental Well-being Scale (SWEMWBS) [31,32]. The scale has demonstrated good reliability (α=.84) and validity in adolescent and young adult populations [33,34]. Depression was measured by the 20-item Center for Epidemiological Studies Depression Scale (CES-D) [35]. The CES-D demonstrates high correlations with other depression measures and excellent internal consistency (α=.85) [35]. Anxiety was measured by

the Generalised Anxiety Disorder 7-item Scale (GAD-7) [36]. The scale has demonstrated excellent reliability (α=.92) and validity in adults [37] and adolescents [38]. Self-compassion was measured by the Self-Compassion Scale-Short Form (SCS-SF) [39]. The scale has demonstrated good reliability (α >.86) in an adolescent sample [40]. Stress was measured by the 10-item Perceived Stress Scale (PSS-10) [41,42]. The PSS-10 scale has demonstrated excellent psychometric properties compared to other stress measures, with good reliability and validity [43]. Sleep quality was measured by the single-item Sleep Quality Scale (SQS) [44]. The SQS has been shown to have excellent concurrent and convergent validity with other lengthier sleep scales and has been demonstrated to be effective in determining clinically meaningful changes in sleep quality. User engagement was assessed by the app Subjective Quality subscale and the Perceived Impact subscale of the end-user version of the uMARS measure [45]. The Subjective Quality subscale score consists of four items that determine user experience (e.g., Would you pay for this app?"). The Perceived Impact subscale score is derived from 6 items measuring the impact of using the app on knowledge, attitudes, and intentions. The uMARS demonstrates good internal reliability (α=.90), and the subscales demonstrate moderate reliability (α=.71 and .80) [45]. In addition to the uMARS, participants also answered how many modules of the *Whitu* app they completed at each time point (1-7 modules) and provided brief qualitative feedback about their experience of using the app via an open-ended question in REDCap®.

Data Analysis

Using Gpower [46], we estimated a sample size of 90 participants (45 per treatment arm) would provide an effect size of *f*=0.155 for between group improvement in well-being using the WHO-5 index using a mixed analysis of variance (ANOVA) including within (three time points) and between (two groups) subject effects, with 90% power and at a two-sided

significance level of 5%. This effect size relates to the between-group improvement in well-being found in a previous study of a web-based positive psychology intervention for mildly depressed adults [47]. To ensure cultural acceptability of the app, we planned to recruit at least 36 (40%) young people of Māori and Pacific Island ethnicity. Baseline characteristics were summarized using means and standard deviations or numbers and percentages. Repeated measures ANOVA was used with linear mixed models to include participants missing data at any of the three time points. The primary analysis aimed to determine whether changes in psychological outcomes were the result of the interaction between the intervention group and time, with post-hoc tests to assess pairwise comparisons of groups at each time point and within-group changes over time. Cohens f^2 was calculated as a measure of effect size for the group by time interaction [48]. The primary comparisons of interest were between group differences at 4 weeks and 3 months, with results presented as marginal mean differences, 95% CIs and p-values. Data were analysed using Stata® software version 17, and statistical significance was set at $p<0.05$. Qualitative feedback was independently extracted and analysed by two authors (HT and AS) using directed content analysis [49]. Data was examined to the point of thematic saturation and any discrepancies in coding were resolved by consensus.

Patient and Public Involvement

Whitu was actively co-designed with New Zealand young people during the COVID-19 pandemic [29]. However, no patients were involved in setting the research question or in developing plans for recruitment, design, implementation and dissemination of the results of the study.

Results

Participant characteristics

Of the 299 individuals who expressed interest, the first 90 eligible participants who met criteria were recruited to the study (45 per arm) between November 2020 and January 2021. One participant withdrew from the intervention arm without using the app due to technical difficulties or choice, four from the same arm were lost to follow-up at four weeks and another at three months. Only one participant was lost from the control arm at four weeks. Further details are presented in the CONSORT flow diagram (Figure 2).

Figure 2: CONSORT flow diagram

Participants ranged between 16 and 30 years, with a mean age of 23.8 years (SD 3.8). The majority of participants were female (n=79; 87.8%) and were students (n=59; 69.6%). Around a third reported having chronic health conditions including anorexia, anxiety, asthma, bipolar disorder, depression, eczema, epilepsy, hay-fever, hyperthyroidism, insomnia, migraines and polycystic ovarian syndrome. Participant demographics were similar between the intervention and control arm, apart from there being a greater proportion of participants reporting health conditions or medication use in the intervention arm and more participants of Pacific ethnicity in the waitlist arm. Further details are presented in Table 2.

Table 2: Participant demographics

Characteristics	Whitu app (N=45)	Waitlist control (N=45)	Total (N=90)
Age (years); mean (SD)	22.71 (3.67)	24.64 (3.74)	23.68 (3.81)
Gender			
Female	40 (88.9%)	39 (86.7%)	79 (87.8%)
Male	3 (6.7%)	6 (13.3%)	9 (10.0%)
Non-binary	2 (4.4%)	0	2 (2.2%)
Ethnicity *			
New Zealand European	14 (31.1%)	11 (24.4%)	25 (27.8%)
Māori	22 (48.9%)	17 (37.8%)	39 (43.3%)
Pacific	2 (4.4%)	9 (20.0%)	11 (12.2%)
Asian	5 (11.1%)	4 (8.9%)	9 (10.0%)
Other ethnic groups	2 (4.4%)	4 (8.9%)	6 (6.7%)
Occupation			
Paid work	16 (35.6%)	15 (33.3%)	31 (34.4%)
Student	29 (64.4%)	30 (66.7%)	59 (65.6%)
Reported having a health condition	18 (40.0%)	12 (26.7%)	30 (33.3%)
Reported taking medications	14 (31.1%)	6 (13.3%)	20 (22.2%)
Reported previous related app use**	10 (22.2%)	11 (24.4%)	21 (23.3%)

*Data are displayed as N (%), unless otherwise stated. *Pacific including: Samoan (n=6), Tongan (n=4), Fijian/Tuvaluan (n=1); and Asian including: Chinese (n=3), Indian (n=3), NZ Sri-Lankan (n=1), Indonesian (n=1), Taiwanese (n=1); **Apps previously used included Calm (n=7), Headspace (n=13) and Insight (n=1)*

Changes in outcome measures over time

Results presented in Table 3 demonstrate that the intervention had a significant effect, as observed by a significant time by group interaction, on emotional (p=0.04) and mental (p=0.008) well-being, stress (p=0.001) and self-compassion (p=0.003). Measures of well-being and self-compassion were significantly higher and stress was significantly lower in the intervention group at both the 4-week and 3-month follow-up. The interaction between group and time on depression, anxiety and sleep did not reach statistical significance. However, differences between groups indicated evidence of better outcomes for those in the intervention group, with lower levels of depression (significant at both follow-ups) and anxiety (significant at 3-months) and higher sleep scores (significant at both follow-ups) being observed, compared to the waitlist controls. All outcome measures significantly improved over time within the intervention group ($p<0.05$; supplementary Table 1). There were no significant differences in outcome measures over time in the waitlist control group, except for sleep scores, which were higher at both follow-ups compared to baselines, although the effects were smaller compared to the intervention group (supplementary Table 1). Further details are presented in Table 3, Figure 3 and Supplementary Table 1.

Table 3: Comparisons between groups in outcome measures over the study period

Outcome	Whitu app (N=45) Mean (SD)	Waitlist control (N=45) Mean (SD)	Marginal mean difference Whitu vs control (95% CI)	*P value*	*Group by time interaction P value*	*Cohen's f^2 effect Size*
Emotional well-being (WHO-5)						
Baseline	50.13 (20.42)	46.84 (23.78)	3.29 (-5.69, 12.27)	0.473		
4 weeks	55.28 (23.03)	42.13 (21.02)	13.19 (3.96, 22.42)	**0.005**	**0.043**	*$f^2 = 0.050$*
3 months	60.51 (18.70)	47.09 (22.74)	13.77 (4.50, 23.03)	**0.004**		
Mental well-being (SWEMBS)						
Baseline	22.36 (5.06)	22.24 (5.16)	0.11 (-2.00, 2.23)	0.918		
4 weeks	24.69 (4.98)	22.27 (5.04)	2.44 (0.27, 4.61)	**0.027**	**0.008**	*$f^2 = 0.077$*
3 months	24.58 (4.95)	21.70 (5.47)	3.01 (0.82, 5.20)	**0.007**		
Depression (CES-D)						
Baseline	20.71 (12.56)	22.31 (11.51)	-1.60 (-6.30, 3.10)	0.504		
4 weeks	15.72 (10.15)	21.56 (11.54)	-5.34 (-10.14, -0.53)	**0.030**	0.061	*$f^2 = 0.049$*
3 months	16.26 (9.42)	23.07 (12.15)	-6.62 (-11.43, -1.82)	**0.007**		
Anxiety (GAD-7)						
Baseline	9.38 (5.87)	9.42 (5.36)	-0.04 (-2.21, 2.12)	0.968		
4 weeks	6.54 (4.76)	8.56 (5.74)	-1.89 (-4.11, 0.33)	0.096	0.060	*$f^2 = 0.047$*
3 months	6.05 (4.22)	8.48 (5.15)	-2.31 (-4.54, -0.08)	**0.042**		
Stress (PSS-10)						
Baseline	21.84 (7.08)	21.62 (7.07)	0.22 (-2.63, 3.07)	0.878	**0.001**	*$f^2 = 0.108$*
4 weeks	16.62 (6.34)	21.42 (7.24)	-4.69 (-7.61, -1.76)	**0.002**		

3 months	17.33 (6.32)	21.41 (7.29)	-3.85 (-6.77, -0.91)	**0.010**		
Self-compassion (SCS-SF)						
Baseline	2.77 (0.68)	2.69 (0.60)	0.08 (-0.19, 0.35)	0.554		
4 weeks	3.21 (0.55)	2.68 (0.66)	0.56 (0.28, 0.83)	**<0.001**	**0.003**	$f^2 = 0.094$
3 months	3.11 (0.73)	2.82 (0.66)	0.31 (0.03, 0.59)	**0.028**		
Sleep (SQS)						
Baseline	5.20 (2.05)	4.84 (2.17)	0.36 (-0.51, 1.23)	0.423		
4 weeks	6.90 (1.93)	5.82 (2.23)	1.13 (0.24, 2.02)	**0.013**	0.141	$f^2 = 0.084$
3 months	7.05 (1.85)	6.14 (2.31)	0.92 (0.03, 1.82)	**0.043**		

Figure 3: Marginal mean outcomes by group and study time point

[INSERT FIGURE HERE]

User feedback

Overall, feedback regarding the app was positive, with special mention made by Māori young people regarding features designed to increase cultural appeal such as the introductory 'karanga' (welcome song). Participants expressed diverse, and non-culturally related preferences regarding individual modules, with newly learnt content being most valued. Suggestions for improvement included the use of shorter videos, improved navigation and greater flexibility with reminders (currently set at once per day). Six users with older mobile phones experienced some technical difficulties, but were still able to use the app. Key themes and examples of participant feedback are provided in Table 4. Usability scores for Whitu are also provided in Table 5.

Table 4: Participant feedback

Theme	Examples
Most useful modules or features	"I found the relax one most helpful. I just really enjoy the guided meditation aspect, the main thing that draws me to these apps. Lovely app, will definitely use again" (Participant 346) "I found the 'be thankful' module the most helpful. I liked this one as it made me stop and consciously focus on the positive aspects of my life" (Participant 327) "This is a well-thought out app and will go on to help many individuals like myself. I feel like i should make a special mention of the karanga at the beginning of the app when i first opened and downloaded it. As a young Māori woman, being called into the app and have it welcome all my problems and grief instantly sparked a spiritual connection for me and i instantly felt at ease and felt safe enough to embark on my healing and wellbeing journey. I also enjoyed the constant use of Te Reo Māori and the progress of watching my Puriri tree grow throughout the 4 weeks. It was a pleasant surprise and so culturally inclusive. The voice overs were pleasant to listen to, the videos, sounds and effects captivating. The

	best app after what was such a rollercoaster year! Thank you!" (Participant 376)
Suggestions for improvement	"Make the videos shorter somehow, I think young people nowadays have short attention spans... including me" (Participant 308) "I did find it was sometimes tricky to find the follow up activities I was supposed to do - these could be better signposted/reminders could link to them directly" (Participant 354) "The daily reminder is good, but often came at a time when I was busy! Maybe a second reminder or setup as part of a daily routine" (Participant 333)
Technical difficulties	"On old phone, when completing modules there was graphical glitching (buttons and images being in the wrong place, the background video overlay being stuck in place between menus).There was also some issues with the video. Sometimes it just wouldn't play until I restarted the app" (Participant 335) "Now that I check the app it has logged my progress with Module 2 but I did not find that right after I had completed it" (Participant 337)

Table 5: Usability for n=38 participants in the intervention group using the Whitu app*

Measures	4 weeks (N=38**)	3 months (N=37**)
uMARS (score range 1-5)		
Subjective app quality score	4.45 (0.72)	4.38 (0.79)
Perceived impact: Awareness	3.89 (0.95)	4.00 (1.03)
Perceived impact: Knowledge/understanding	3.76 (1.15)	3.86 (1.03)
Perceived impact: Attitudes	3.58 (1.13)	3.46 (1.28)
Perceived impact: Intention to change	3.71 (1.09)	3.57 (1.34)
Perceived impact: Help seeking	3.66 (1.07)	3.57 (1.07)
Perceived impact: Behavior change	3.63 (1.10)	3.76 (1.19)

Discussion

Overall Findings

To our knowledge, this is the first randomised controlled trial of a well-being app for young people undertaken during the COVID-19 pandemic and it addresses the clear gap in the COVID-related literature (i.e. the lack of studies to address anticipated psychological effects of the pandemic) highlighted by Gilbody et al [50]. Our results indicate that Whitu is an effective, usable and acceptable composite digital health intervention with which to improve multiple aspects of young people's health including well-being, self-compassion, and sleep, and to reduce anxiety, depression and stress. Benefits were evident at four weeks and sustained at three-month follow-up. The fact that well-being in the intervention group actually improved during a pandemic is also clinically significant. Based on uMARS scores (Table 4), usability of Whitu was high, and greater than that of recently developed mental health apps and established norms [51,52].

Comparison with Previous Research

Our findings are consistent with recent review evidence that mindfulness and multi-component interventions are most effective at improving the well-being of clinical and non-clinical populations [53]. Despite the potential floor effect with a non-clinical population, users of Whitu reported significantly improved symptoms of anxiety and depression. Resulting effect sizes were similar to the small to moderate effect sizes of individually-targeted digital interventions for treating these conditions [54], suggesting that Whitu may be beneficial for clinical populations. Since the onset of the pandemic, a rapid review of existing digital mental health interventions has ascertained they are usable, safe, acceptable and likely to be effective in ameliorating at least some of the psychological consequences of lockdown [54]. However, only one other RCT of a four-week mindfulness-based intervention delivered to

Chinese university students via Zoom® and asynchronous WeChat video and audio recordings has actually been undertaken and shown to improve symptoms of anxiety and depression compared with technology-based social support [55].

Given reports that only 3.9% of individuals who download health apps use them for a median of 15 days more than two weeks [56] and that only 0.5 to 28.7% actually complete them [57], the relatively high efficacy and acceptability of Whitu may be related to its intentionally time-limited design. Encouraging young people to learn new self-management strategies via the app and then practice them in the real world should also help with generalisation of these skills [57]. Although some may argue that an app designed to support young people during the pandemic may be of limited chronological relevance, previous evidence from earthquake survivors in New Zealand suggests that psychological effects of major events are likely to be delayed, with rates of problems increasing by between 25-40% even after two year [58,59]. Given the protracted nature of the current pandemic, its true psychological cost will only be obvious in retrospect.

Strengths and Limitations

Strengths of this study include the adequate power, overall low drop-out rate (less than the typical drop-out rate of 25% during studies of other mobile health interventions) [60] and small amount of missing data. In addition, given our desire to develop a culturally safe and relevant app, the appeal of Whitu to Māori and Pacific young people and its efficacy with these groups is reassuring and likely to reduce existing health inequities, thereby honouring New Zealand's commitment to the Treaty of Waitangi [61,62]. Weaknesses of the study include the lack of blinding of participants, inclusion of fewer male participants and use of self-reported outcome measures. It is also possible that group differences may have been smaller if an

active control had been used instead of a waitlist control. As Whitu was designed to preserve well-being in the general population (rather than treat existing mental health issues) and in order to limit confounding from concurrent psychological therapies, inclusion in the study was limited to individuals not currently receiving mental health treatment. As such, its applicability to those already experiencing mental health issues remains unproven and further research with this group would be worthwhile. Around a third of participants reported having an existing health condition and this is in keeping with previous evidence that around 18% of New Zealand high school students and up to 45% of adults live with chronic health conditions [63, 64]. Although it is possible that individuals with pre-existing health issues were more likely to enrol in a study involving the use a new health app, the studied population appears to be representative of young people in the community. A greater proportion of participants dropped out from the intervention group than the control group and, although characteristics of those who dropped out and those who continued within each group were similar (please see Table 1 and Figure 1 below), our primary analysis may be biased by this missing data. For example, if reasons for dropout (which were unavailable) were related to worse outcomes, this might have potentially overstated the positive effects of the intervention. Although none of these individuals who dropped out provided feedback on their experience at the end of the study, this difference may reflect challenges in using, or lack of appeal of, eHealth interventions for some young people. Our results need to be replicated in other settings (such as schools) and with young people below 16 years of age to ensure their generalisability. Evaluation of Whitu's efficacy with higher-risk groups such as young people with long-term physical conditions [16] and more objective measures of app use and clinical outcomes would be valuable. Finally, future research would benefit from formal economic analysis to bridge the gap between researcher interests and policymakers [65].

Conclusions

For the moment, this study provides preliminary evidence that Whitu is a clinically effective and scalable means of improving the well-being and mental health of young people during the COVID-19 pandemic.

Contributorship statement

HT and ASS conceived the research question. HT, ASS, ALB, DL, KS, EM, NC and AC designed the study. AC performed sample size calculations. HT and ASS applied for ethics approval and registration of the study. ALB, DL, KS, EM and NC undertook participant recruitment. ALB and DL set up and executed REDCap data collection. ASS, ALB and AC analysed quantitative data. HT and DL analysed qualitative data. EM and NC provided cultural oversight during the study. HT wrote the initial version of this manuscript and ASS, ALB, DL, KS, EM, NC and AC contributed to critical edits. All authors approved the final version of the manuscript. The corresponding author (HT) acts as the guarantor, accepts full responsibility for the work, and attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

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Competing interest statement

No competing interest.

Data sharing statement

Deidentified, collated data from this study are presented in this paper. Individual data sets are not available for sharing as participants did not provide consent for this information to be shared. Any other details of the study procedure are available from the lead author on request (please email h.thabrew@auckland.ac.nz).

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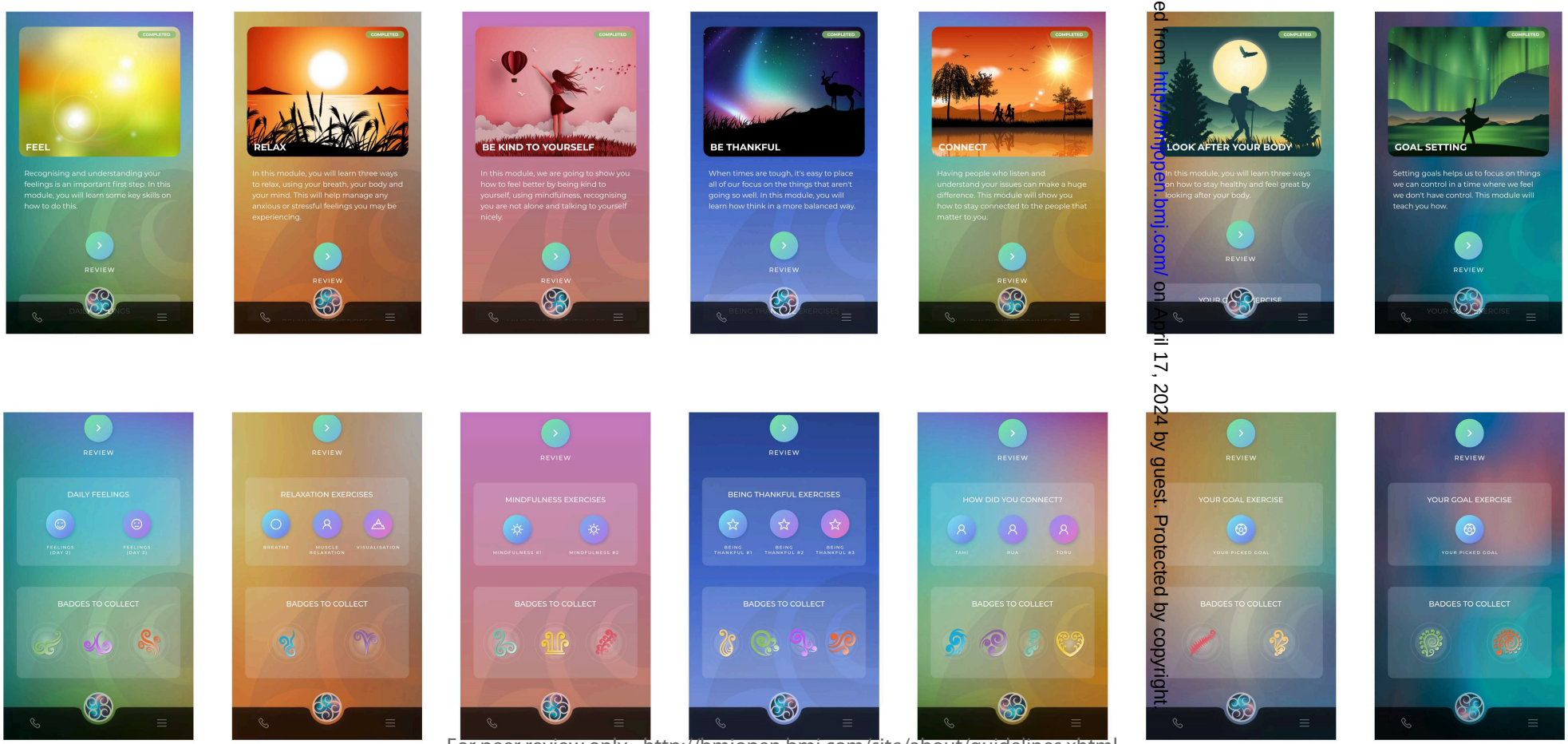

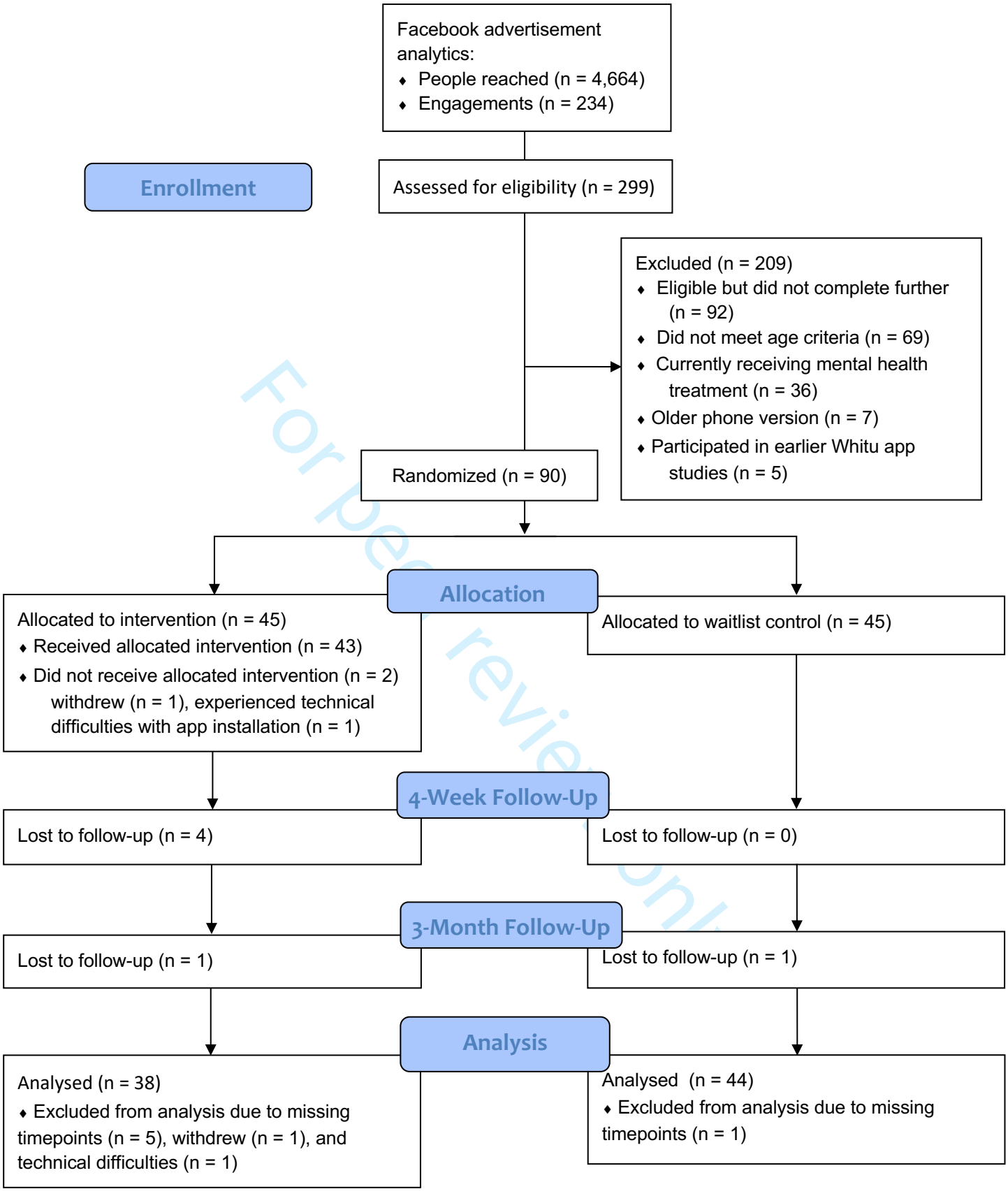

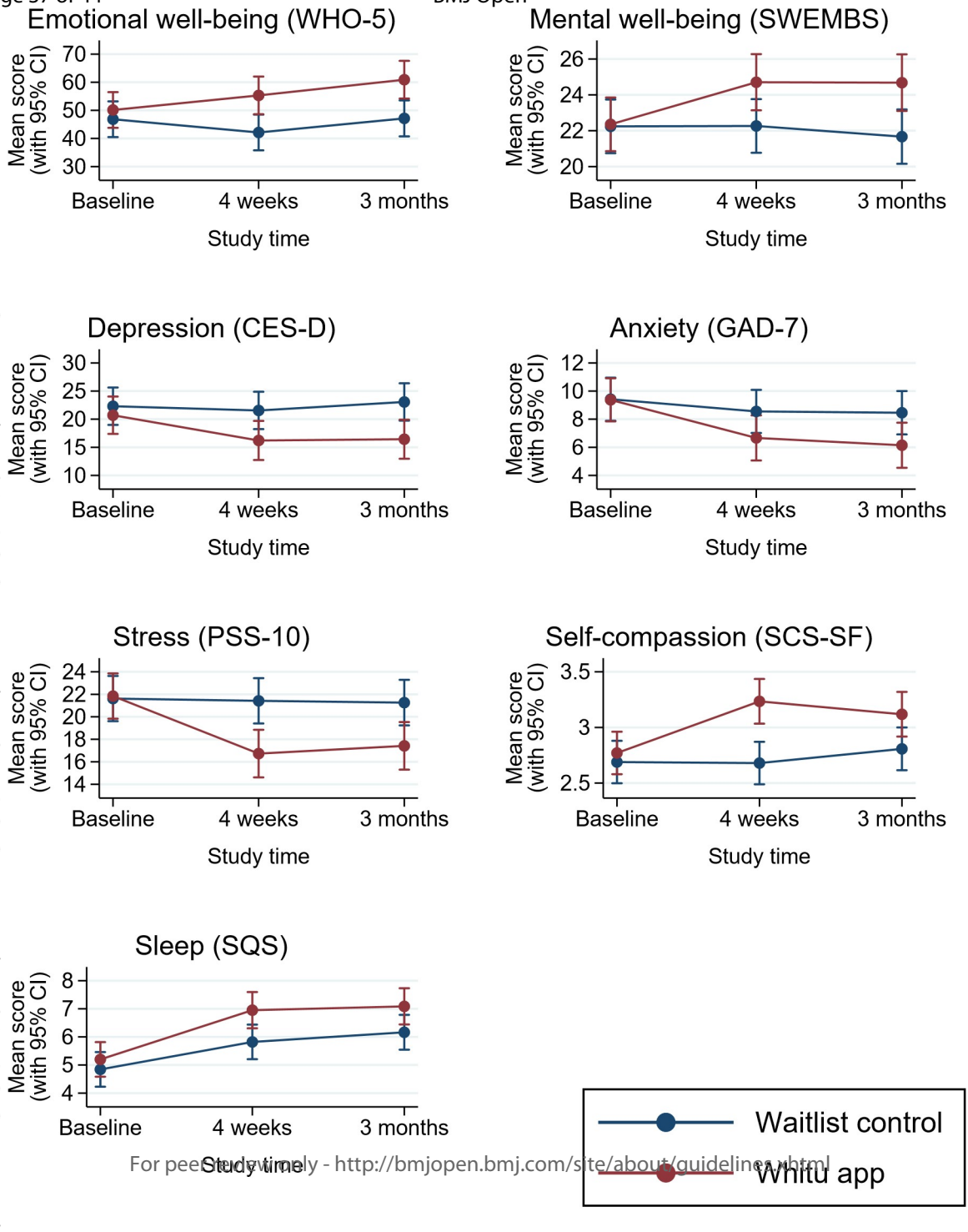

Supplementary table 1: Within group changes in outcome measures over time

Outcome	Whitu app (N=45)			Waitlist control (N=45)			*Group by time Interaction P value*
	Mean (SD)	Mean difference (95% CI)	*P value*	Mean (SD)	Mean difference (95% CI)	*P value*	
Emotional well-being (WHO-5)							
Baseline	50.13 (20.42)	Ref	Ref	46.84 (23.78)	Ref	Ref	
4 weeks	55.28 (23.03)	5.19 (-1.51, 11.89)	0.129	42.13 (21.02)	-4.71 (-11.06, 1.64)	0.146	**0.043**
3 months	60.51 (18.70)	10.78 (4.08, 17.48)	**0.0002**	47.09 (22.74)	0.30 (-6.10, 6.70)	0.927	
Mental well-being (SWEMBS)							
Baseline	22.36 (5.06)	Ref	Ref	22.24 (5.16)	Ref	Ref	
4 weeks	24.69 (4.98)	2.35 (0.95, 3.76)	**0.001**	22.27 (5.04)	0.02 (-1.30, 1.35)	0.974	**0.008**
3 months	24.58 (4.95)	2.33 (0.91, 3.74)	**0.001**	21.70 (5.47)	-0.57 (-1.92, 0.77)	0.404	
Depression (CES-D)							
Baseline	20.71 (12.56)	Ref	Ref	22.31 (11.51)	Ref	Ref	
4 weeks	15.72 (10.15)	-4.29 (-7.64, -1.34)	**0.005**	21.56 (11.54)	-0.76 (-3.73, 2.22)	0.619	0.061
3 months	16.26 (9.42)	-4.27 (-7.42, -1.12)	**0.008**	23.07 (12.15)	0.76 (-2.22, 3.73)	0.619	
Anxiety (GAD-7)							
Baseline	9.38 (5.87)	Ref	Ref	9.42 (5.36)	Ref	Ref	0.060
4 weeks	6.54 (4.76)	-2.71 (-4.16, -1.26)	**<0.001**	8.56 (5.74)	-0.87 (-2.23, 0.50)	0.215	
3 months	6.05 (4.22)	-3.23 (-4.68, -1.78)	**<0.001**	8.48 (5.15)	-0.96 (-2.34, 0.42)	0.172	
Stress (PSS-10)							
Baseline	21.84 (7.08)	Ref	Ref	21.62 (7.07)	Ref	Ref	
4 weeks	16.62 (6.34)	-5.11 (-7.14, -3.09)	**<0.001**	21.42 (7.24)	-0.20 (-2.11, 1.71)	0.838	**0.001**
3 months	17.33 (6.32)	-4.43 (-6.45, -2.40)	**<0.001**	21.41 (7.29)	-0.36 (-2.29, 1.57)	0.716	

Self-compassion (SCS-SF)							
Baseline	2.77 (0.68)	Ref	Ref	2.69 (0.60)	Ref	Ref	
4 weeks	3.21 (0.55)	0.46 (0.27, 0.66)	**<0.001**	2.68 (0.66)	-0.01 (-0.20, 0.18)	0.922	**0.003**
3 months	3.11 (0.73)	0.35 (0.15, 0.55)	**0.001**	2.82 (0.66)	0.12 (-0.07, 0.31)	0.216	
Sleep (SQS)							
Baseline	5.20 (2.05)	Ref	Ref	4.84 (2.17)	Ref	Ref	
4 weeks	6.90 (1.93)	1.75 (1.17, 2.33)	**<0.001**	5.82 (2.23)	0.98 (0.43, 1.52)	**<0.001**	0.141
3 months	7.05 (1.85)	1.89 (1.31, 2.46)	**<0.001**	6.14 (2.31)	1.32 (0.77, 1.87)	**<0.001**	

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	1
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	5
	2b	Specific objectives or hypotheses	6
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	7
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	7
	4b	Settings and locations where the data were collected	7
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	8
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	9
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	10
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	7
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	7
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	7
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	7
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	7

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	N/A
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	10
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	11
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	12
	13b	For each group, losses and exclusions after randomisation, together with reasons	12
Recruitment	14a	Dates defining the periods of recruitment and follow-up	12
	14b	Why the trial ended or was stopped	N/A
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	13
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	14
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	15
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	15
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	16-17
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	14
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	19
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	19
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	19
Other information			
Registration	23	Registration number and name of trial registry	4
Protocol	24	Where the full trial protocol can be accessed, if available	4
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	20

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

TIDieR Template for Intervention Description and Replication

The TIDieR (Template for Intervention Description and Replication) Checklist*:

Information to include when describing an intervention and the location of the information

Item number	Item	Where located **	
		Primary paper (page or appendix number)	Other † (details)
	BRIEF NAME		
1.	Provide the name or a phrase that describes the intervention. **A well-being app to support young people during the COVID-19 pandemic**	1	
	WHAT		
2.	Describe any rationale, theory, or goal of the elements essential to the intervention. **A well-being app that, as its name suggests, contains seven positive psychology, CBT and psychoeducation-based modules to help young people (i) recognise and rate emotions, (ii) learn relaxation and mindfulness, (iii) practice self-compassion and (iv) gratitude, (v) connect with others, (vi) care for their physical health and (vii) engage in goal-setting. It can be completed within a week or as desired.**	6	
3.	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL). **Whitu: seven ways in seven days is a free-to-user mobile application (app) that is available on the App Store (https://apps.apple.com/nz/app/whitu/id1508135602?ign-mpt=uo%3D4) and Google Play Store (https://play.google.com/store/apps/details?id=com.carbonimagineering.whitu) for New Zealand residents.**	8	
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities. **Prospective randomised controlled trial of Whitu against waitlist control, with 45 participants in each arm. 90 New Zealand young people aged 16-30 recruited via a social media advertising**	6	

	campaign. Primary outcomes were changes in well-being on the World Health Organisation 5-item well-being index (WHO-5) and short Warwick-Edinburgh mental well-being scale (SWEMWBS). Secondary outcomes were changes in depression on the Centre for Epidemiological Studies Depression Scale (CES-D), anxiety on the Generalised Anxiety Disorder seven item scale (GAD-7), self-compassion on the Self Compassion Scale- Short Form (SCS-SF), stress on the 10-item Perceived Stress Scale (PSS-10) ,sleep on the single-item Sleep Quality Scale (SQS) and user engagement on the end-user version of the Mobile Application Rating Scale (uMARS) and via qualitative feedback. Outcomes were evaluated at baseline, four weeks (primary study endpoint) and three months, and analysed using linear mixed models with group, time and a group-time interaction.		
	WHO PROVIDED		
5.	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given. **N/A (self-help intervention (app) utilised without therapeutic support)**		
	HOW		
6.	Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group. **App downloaded onto participants' mobile phones and individually used.**	7_	
	WHERE		
7.	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features. **Intervention completed in participants' homes**.	7_	
	WHEN and HOW MUCH		
8.	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	7_	

	App designed to be flexibly used, but ideally completed within a week. Users given up to 4 weeks to complete the intervention.		
	TAILORING		
9.	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how. **Users could complete most modules in any order that they wished and repeat preferred exercises as often as desired.**	7	
	MODIFICATIONS		
10.‡	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how). **N/A**		
	HOW WELL		
11.	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them. **N/A (as the intervention was designed to be flexibly used, this was not relevant)**		
12.‡	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned. **N/A**		

** **Authors** - use N/A if an item is not applicable for the intervention being described. **Reviewers** – use '?' if information about the element is not reported/not sufficiently reported.

† If the information is not provided in the primary paper, give details of where this information is available. This may include locations such as a published protocol or other published papers (provide citation details) or a website (provide the URL).

‡ If completing the TIDieR checklist for a protocol, these items are not relevant to the protocol and cannot be described until the study is complete.

* We strongly recommend using this checklist in conjunction with the TIDieR guide (see *BMJ* 2014;348:g1687) which contains an explanation and elaboration for each item.

* The focus of TIDieR is on reporting details of the intervention elements (and where relevant, comparison elements) of a study. Other elements and methodological features of studies are covered by other reporting statements and checklists and have not been duplicated as part of the TIDieR checklist. When a **randomised trial** is being reported, the TIDieR checklist should be used in conjunction with the CONSORT statement (see www.consort-statement.org) as an extension of **Item 5 of the CONSORT 2010 Statement.** When a **clinical trial protocol** is being reported, the TIDieR checklist should be used in conjunction with the SPIRIT statement as an extension of **Item 11 of the SPIRIT 2013 Statement** (see www.spirit-statement.org). For alternate study designs, TIDieR can be used in conjunction with the appropriate checklist for that study design (see www.equator-network.org).