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Mindfulness improves psychological health and supports health behaviour cognitions: Evidence from a pragmatic RCT of a digital mindfulness-based intervention

AUTHORS: Masha Remskar, MSc[a,b], Max Western, PhD[b], Ben Ainsworth, PhD[c]

[a]Bath Centre for Mindfulness and Community, Department of Psychology, University of Bath, UK.

[b]Centre for Motivation and Health Behaviour Change, Department for Health, University of Bath, UK.

[c]Digital Interventions Group, Department of Psychology, University of Southampton, UK.

ADDRESS CORRESPONDENCE TO: Masha Remskar, Department for Health, University of Bath, Claverton Down, Bath, BA2 7AY, UK. Email: mr988@bath.ac.uk.

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Statement of contribution

What is already known on this subject?

- Mindfulness-based interventions (MBIs) can be effective in improving wellbeing and mental health in both clinical and general populations. However, the mechanisms through this occurs are underexplored. One of the ways in which MBIs could improve wellbeing is by supporting health-related behaviour. MBIs have been used to support adherence to health behaviour change interventions (e.g., those targeting diet or physical activity). This could be because mindfulness training can affect self-regulatory capabilities, which are crucial for adaptive behaviours and behaviour change.

What does this study add?

- Self-administered digital mindfulness training can improve wellbeing, depression, and anxiety.
- Mindfulness training can adaptively alter motivation and attitudes towards health maintenance.
- Improved psychological health is at least partially due to changes in above mechanistic variables.

Abstract

Background: Mindfulness-based interventions can improve psychological health, yet the mechanisms of change are underexplored. This pre-registered remote RCT evaluated a freely-accessible digital mindfulness programme aiming to improve wellbeing, mental health and sleep quality. Health behaviour cognitions were explored as possible mediators.

Methods: Participants from 91 countries (N= 1247, M_{age}= 27.03 [9.04]) were randomised to 30 days of mindfulness practice or attention-matched control condition. Measures of wellbeing, depression, anxiety, stress, sleep quality, barriers self-efficacy, self-regulation and behavioural predictors (e.g., attitudes and behavioural intentions) were taken at baseline, 1-month (post-intervention) and 2-months (follow-up). Linear regression examined intervention effects between and within groups. Longitudinal mediation analyses explored indirect effects through health behaviour cognitions.

Results: 300 participants completed post-intervention measures. Those receiving mindfulness training reported significantly better wellbeing ($M_{difference}$= 2.34, 95%CIs 0.45 to 4.24, p= .016), lower depression ($M_{difference}$= -1.47, 95%CIs -2.38 to -0.56, p= .002), and anxiety symptoms ($M_{difference}$= -0.77, 95%CIs -1.51 to -0.02, p= .045) than controls. Improvements in wellbeing and depression were maintained at follow-up. Intervention effects on primary outcomes were mediated by attitudes towards health maintenance and behavioural intentions. Mediating effects of attitudes remained when controlling for prior scores in models of depression and wellbeing.

Conclusions: Digital, self-administered mindfulness practice for 30 days meaningfully improved psychological health, at least partially due to improved attitudes towards health behaviours and stronger behavioural intentions. This trial found that digital mindfulness is a promising and scalable wellbeing tool for the general population, and highlighted its role in supporting health behaviours.

Keywords: Mindfulness, Digital health, Wellbeing, Depression, Self-regulation, Behaviour change

Introduction

Mindfulness-based interventions (MBIs), which facilitate structured practice of non-judgementally paying attention to the present moment (Shapero et al., 2018), have benefits to wellbeing and quality of life. They are commonly used to improve psychological symptoms and prevent relapse in clinical populations (Hoffman et al., 2010; McCartney et al., 2021), or advised as complementary treatment in managing long-term conditions (Bohlmeijer et al., 2010; Piet et al., 2012; Walker et al., 2010). MBIs can also act as preventative tools for improving psychological wellbeing, reducing stress, and improving sleep quality in the general population (Chiesa & Serretti, 2009; Lomas et al., 2019; Rusch et al., 2019).

The increasing use of digital technology to support healthcare has enabled the translation of evidence-based MBI principles into more accessible, wide-reaching, and inclusive digital tools. Empirical evidence suggests that digital MBIs can deliver benefits to attention regulation and psychological health comparable to interventions delivered in-person, such as 8-week mindfulness-based stress reduction (MBSR) programs (Mrazek et al., 2019). Digital MBIs have been found to reduce stress with a moderate effect size in a meta-analysis by Jayawardene and colleagues (2017), alleviate symptoms of depression and anxiety with similar potency (Boettcher et al., 2014; Querstret et al., 2018), and improve sleep—itself strongly associated with mental health outcomes (Jiang et al., 2021; Scott et al., 2021). The availability of digital mindfulness is increasing too: A recent review identified over 600 commercial app-based MBIs in European mobile app stores (Schultchen et al., 2021), some of which explicitly referenced standardised mindfulness and behaviour change techniques. While this increased reach is welcome and necessary in modern public health strategies (WHO, 2021), care must be taken to ensure that benefits are not limited to individuals with increased resources (e.g. financial, health literacy, time) and ensure that benefits are accessible to those most in need of psychological support (Hunt & Eisenberg, 2010; Williams et al., 2016).

Understanding specific mechanisms through which MBIs support psychological health not only advances theoretical understanding, but guides the development and optimisation of future interventions to make them maximally engaging and effective. Putative therapeutic mechanisms include supporting health-related behaviours, such as regular physical activity, a healthy diet, and good sleep hygiene. Evidence shows that people with high dispositional mindfulness are more aware of the importance of positive health behaviours (Dutton, 2008), compared to those less mindful, and a meta-analysis of over 30000 participants found those higher in trait mindfulness reported engaging in more health behaviours than their less mindful counterparts (Sala et al., 2020). In turn, evidence shows that both engagement in health behaviours and being more dispositionally mindful are associated with better psychological health (e.g., Singh et al.'s [2023] meta-review evidencing the positive effects of physical activity on mental health; Tomlinson et al., 2018, respectively). In two recent RCTs in primary care populations, individuals who received in-person mindfulness training demonstrated improved engagement in health-related behaviours (Gawande et al., 2019; Nymberg et al., 2021; see Remskar et al., 2023, for a review). These effects are yet to be explored in digital MBIs.

Mindfulness training may support health behaviours by affecting key psychological processes and cognitions required for engagement. Self-efficacy, one's perceived capacity to engage in a behaviour or reach a goal (Bandura, 1986), and self-regulation (i.e., "the ability to adaptively regulate one's attention, emotions, cognition, and behaviour"; Schuman-Olivier et al., 2020, p. 372), both predict behaviour (change) according to established theoretical models (e.g., Ajzen's [1991] Theory of Planned Behaviour; Michie et al., 2011; Ryan & Deci, 2000). Cross-sectional evidence finds that higher trait mindfulness is associated with greater self-efficacy (Neace et al., 2022), better coping with obstacles or pain (Luberto et al., 2014; Liu et al., 2012), and more skilful self-regulation (Kadziolka et al., 2016). Hence, mindfulness training through MBIs may develop self-regulatory abilities, including non-judgement, acting with awareness (Black et al., 2012), emotion recognition and behavioural regulation (Luberto et al., 2014), positive reappraisal (Hanley & Garland, 2014), and intrinsic motivation (Ruffault et al., 2016). Developing self-regulatory skills and cognitions in this way facilitates the recognition of existing thought patterns and can prompt adaptive reappraisal of own states and attributions for them (e.g., beliefs about controllability of illness; Leventhal, 1980). This crucially shapes what behaviours are performed in response, and the health-related outcomes that follow (see Hagger & Orbell, 2022, for an extended theoretical framework).

This research aimed to use a randomised controlled trial design to build on cross sectional evidence between mindfulness, psychological health, and health behaviour cognitions. It examined how digital mindfulness training affects psychological wellbeing, depression, anxiety, stress and sleep quality, and whether these changes are mediated by changes in health behaviour-related self-efficacy, self-regulation and behavioural predictors from the Theory of Planned Behaviour. Figure 1 presents the theoretical process model the study proposes to test.

Objectives & hypotheses

Specifically, the study aimed to:

1. Investigate the effects of self-administered, freely available digital mindfulness training through the Medito platform for 30 days on psychological health (i.e., wellbeing, symptoms of depression, anxiety and stress, and perceived sleep quality).
   We hypothesised that participants randomised to the intervention condition will report greater improvements in all psychological health outcomes relative to control condition.
2. Examine the effects of this training on health behaviour-related self-efficacy, self-regulation and predictor components from the Theory of Planned Behaviour (i.e., attitudes, social norms, perceived behavioural control and behavioural intentions).
   We hypothesised that participants randomised to the intervention condition will report greater improvement in all health behaviour cognitions relative to control condition.
3. Explore whether any changes in psychological health (from aim 1) are mediated by changes in health behaviour cognitions (from aim 2).

These analyses were exploratory but based on theoretical frameworks we hypothesised that any cognition with significant changes during the intervention period (T1-T2) will at least partially mediate the effects of intervention condition on psychological health outcomes at T3.

Methods

Design

This was a prospective randomised controlled trial (RCT) with a 2 (Condition; mindfulness or active control; between-subjects) x 3 (Time; within-subjects; T1, T2, T3) mixed factorial design. The study was pre-registered with the Open Science Framework (https://osf.io/8gncp/) and approved by the University of Bath Psychology Research Ethics Committee (PREC #22-015).

Participants

Adults aged 18 or above who had not previously used digital mindfulness platform Medito were eligible to participate. We aimed for a minimum required sample size of 274 participants to detect differences between conditions at post-intervention (Time 2) at 80% power, 0.05 significance level and expected effect size $f = .17$ (based on prior mindfulness intervention research; Ainsworth et al., 2022). Given the entirely remote format of the RCT we expected low retention (~30%; Torous et al., 2020), so our recruitment target was 1000 participants at baseline.

Procedure

Recruitment was open between April and June 2022. Participants were recruited from adverts placed via social media and during the sign-up process of the Medito app. Users completed an eligibility questionnaire, informed consent form, demographics and baseline (Time 1) measures before automatic randomisation (1:1) via online survey software. Participant app usage was linked with survey responses through anonymised codes. Weekly reminder emails aimed to support engagement in both conditions during the active phase of the study (on days 8, 15, 22 and 29) as well as intervention instructions and personalised survey links at post-intervention (Day 31; T2) and follow-up (Day 61; T3). Participants who completed all three survey timepoints were eligible for a prize draw for 100 USD. The whole workflow (including random sequence generation, allocation to condition, and sending personalised links to T2 and T3 surveys) was automated and required no researcher involvement, which preserved allocation concealment and protected against researcher-induced risk of bias.

Retention and adherence

A total of 1268 eligible participants provided informed consent and were randomised after completing baseline questionnaires. Fifteen participants (1.1%; 2 intervention, 13 control) withdrew during the course of the study (Figure 2). In the baseline sample of 1253, 6 responses had invalid data, leaving the final N = 1247 (618 intervention, 629 control). A further 86 (6.9%; 46 intervention, 40 control) did not formally withdraw but unsubscribed from automated emails, so could not access personalised T2 and T3 survey links. A subset of 300 participants provided data at our primary endpoint post-intervention, exceeding our power calculation (24.1% retention rate at T2; 155 intervention, 145 control) and 202 responded to follow-up measures (16.2% retention rate at T3; 99 intervention, 103 control). A full CONSORT flow diagram is presented in Figure 2.

Intervention

Mindfulness condition

The mindfulness intervention consisted of individual mindfulness meditation practice guided by audio files accessed in the Medito mobile application, which is a free commercially available app for iOS and Android devices (https://meditofoundation.org/). After randomisation, participants were asked to practice 10 minutes daily for 30 consecutive days and complete Medito's '30-Day Challenge', a 30-session course aimed at people with little or no prior mindfulness skills. Each 10-minute session consisted of initial relaxation, intention-setting, a body scan, focused attention using breath as an anchor (majority of the session) and brief reflection on own practice to conclude. Supplementary materials describe the platform in more detail, including the template for intervention description and replication (TIDieR; Hoffmann et al., 2014).

Attention-matched control condition

The control intervention consisted of daily audiobook excerpts from *Alice's Adventures in Wonderland* and *Through the Looking Glass* by Lewis Carroll (Carroll, 1893; 1909). Participants were instructed to "listen to daily 10-minute audio sessions", which they accessed through a section the Medito app specifically added for this trial. It included the two audiobook recordings in the public domain (https://librivox.org/alices-adventures-in-wonderland-by-lewis-carroll/ and https://librivox.org/through-the-looking-glass-by-lewis-carroll/) cut into 10-minute consecutive sections. Audiobook recordings have been previously used and validated as an attention-matched control condition to guided relaxation interventions (Polaski et al., 2021; Zeidan et al., 2015). In our trial, the control condition was designed to match the process of accessing daily sessions, time spent listening, and the act of following along an audio recording for 10 minutes per day—without providing the hypothesised active ingredient of mindfulness training.

Outcome measures

Primary outcomes: Psychological health and sleep quality

Psychological wellbeing was measured with the Warwick-Edinburgh Mental Well-Being Scale (WEMWBS; Tennant et al., 2007), a 14-item questionnaire with a higher total implying better psychological wellbeing (range 0-70, all $\alpha > 0.89$).

Symptoms of depression, anxiety and stress were measured with the Depression, Anxiety and Stress short-form questionnaire (DASS-21; Lovibond & Lovibond, 1995), Rating its 21 statements gives subscale scores of 0-21 for depression, anxiety and stress, where higher scores indicate more severe symptoms (all $\alpha > 0.91$).

Sleep quality was measured with a single item ("How would you rate the quality of your sleep over the past week?"). Participants responded on a slider scale from 0 ("Worst possible sleep") to 10 ("Best possible sleep").

Secondary outcomes: Health behaviour cognitions

Participants were instructed to spend a minute reflecting on the behaviours they engage in to keep themselves physical and mentally healthy and asked to keep those behaviours in mind during the following three questionnaires.

Motivation for engaging in health behaviours was measured with the Treatment Self-Regulation Questionnaire (TSRQ; Pelletier et al., 1997; all $\alpha > 0.81$), a 16-item instrument on which nine controlled subscale items and seven autonomous subscale items give average controlled and autonomous self-regulation scores, 0-7 each. To measure a balance of the two types of regulation (i.e., the Relative Autonomy Index or RAI), the average controlled score is subtracted from average autonomous score.

Health behaviour self-efficacy was measured with the Barriers Self-Efficacy Scale (BARSE; McAuley & Courneya, 1992; all $\alpha > 0.84$). It lists 13 commonly reported obstacles to health behaviour and higher average scores indicate greater self-efficacy (range 0-7).

Behavioural predictors from the Theory of Planned Behaviour (TPB; Ajzen, 1991) were measured with a 12-item TPB questionnaire (TPBQ; Fishbein & Ajzen, 2010; all $\alpha > 0.76$) on attitudes, social norms, perceived behavioural control and behavioural intentions for looking after one's health (3 items each on a scale 0-7). Higher average scores indicate more positive attitudes, greater perceived social expectations, behavioural control, or behavioural intentions.

Data analysis

All analyses were performed in SPSS v27 (IBM Corp, 2020) according to the pre-registered analysis plan (https://osf.io/8gncp/) and followed modified intention-to-treat (ITT) principles, where participants were included in the analysis irrespective of their levels of adherence and engagement to their allocated intervention.

Between-group differences in primary and secondary outcomes at T2 and T3 were assessed with univariate analyses of covariance (ANCOVAs) controlling for baseline scores , following best practice guidelines for this research design (see Twisk et al. [2018] for a discussion on analysing longitudinal RCT designs). Linear mixed models were conducted as a sensitivity analysis (data not shown – see Supplementary materials for model parameters, results, and side-by-side comparison of findings). Since data in the full dataset were not missing completely at random (Little's MCAR test $p = 0.001$), data were not imputed for these analyses.

Longitudinal mediation models were run using the PROCESS macro for SPSS (Hayes, 2022), using a subset of data with T2 responders-only ($N = 300$). In this dataset, missing data displayed no discernible pattern (Little's MCAR test $p = 0.166$), so we imputed missing data using the expectation-maximisation algorithm. We entered condition as the categorical predictor, post-intervention scores for health behaviour cognitions as mediators and follow-up psychological health scores as outcomes, with separate models for each combination of mediator and outcome meeting mediation model criteria (Fritz & Mackinnon, 2007). Repeated analyses controlled for baseline (and post-intervention) mediator and outcome scores, respectively, in so-called "lagged" models. Bootstrapping with 5000 samples was used to verify 95% CIs, where indirect effect CIs not containing zero were considered significant.

Results

Participant characteristics

Baseline demographic information and variable scores are presented in Table 1. Participants came from 91 different countries across all continents, with a majority having no (27%) or limited (36%) meditation experience and only 3% reporting abundant experience. Average baseline psychological wellbeing and sleep quality were moderate, and symptoms of depression, anxiety and stress were all in the normal-to-mild range (Lovibond & Lovibond, 1993).

Responders to T2 surveys, whose data we used in the mediation analyses, had similar demographic profile and baseline scores. In comparison to drop-outs (i.e., participants who only provided data at T1), participants who also responded at T2 were more likely to be older (M_{age} = 28.6 vs 26.5 years; $t_{(414.88)} = -2.81$, $p = .005$) and have more meditation experience (M_{exp} = 2.60 vs 2.19 on a 1-4 scale; $t_{(461.03)} = -5.41$, $p < .001$). Allocation to condition, other demographic characteristics and baseline scores did not differ significantly between dropouts and T2 responders (all $t < 1.78$, $p > .05$).

Primary outcomes: Wellbeing, mental health, and sleep

Primary outcome scores for all timepoints are reported in Table 2, along with between-group comparisons of estimated marginal means (i.e., T2 or T3 values corrected for baseline scores).

At post-intervention, between-group comparisons correcting for baseline scores showed that intervention group had significantly better psychological wellbeing ($M_{difference}$ = 2.34, 95% CIs [0.45, 4.24], $p = .016$), lower symptoms of depression ($M_{difference}$ = -1.47, 95% CIs [-2.38, -0.56], $p = .002$) and anxiety ($M_{difference}$ = -0.77, 95% CIs [-1.51, -0.02], $p = .045$), relative to control. Stress and sleep quality scores did not differ between conditions.

At follow-up, the intervention group maintained better psychological wellbeing ($M_{difference}$ = 3.06, 95% CIs [0.25, 5.87], $p = .033$) and lower depression symptoms ($M_{difference}$ = -1.86, 95% CIs [-3.17, -0.54], $p = .006$), as well as reported better quality of sleep ($M_{difference}$ = 0.68, 95% CIs [0.17, 1.19], $p = .010$), compared to control. Anxiety and stress levels did not differ between conditions.

Secondary outcomes: Health behaviour cognitions

At post-intervention, the intervention group had significantly more positive attitudes towards health maintenance ($M_{difference}$ = 0.33, 95% CIs [0.08, 0.57], $p = .010$), greater perceived behavioural control ($M_{difference}$ = 0.21, 95% CIs [0.01, 0.42], $p = .045$), and firmer behavioural intentions to look after their health ($M_{difference}$ = 0.26, 95% CIs [0.03, 0.50], $p = .029$). Social norms were also different between groups, with intervention condition reporting *lesser* perceived social expectations to maintain health, relative to control ($M_{difference}$ = -0.59, 95% CIs [-0.95, -0.22], p = .002). Conditions had comparable levels of autonomous SR, controlled SR, RAI, and barrier self-efficacy.

At follow-up, intervention participants reported more autonomous SR ($M_{difference}$ = 0.33, 95% CIs [0.02, 0.64], p = .038), and maintained more positive attitudes towards health maintenance ($M_{difference}$ = 0.37, 95% CIs [0.04, 0.71], p = .027). Differences in behavioural intentions to look after one's health were no longer statistically significant ($M_{difference}$ = 0.21, 95% CIs [-0.12, 0.54], p = .219), and there were also no differences in controlled SR, RAI, barriers self-efficacy, social norms, or perceived behavioural control.

Sensitivity analyses for effects of intervention on both primary and secondary outcomes detected largely congruent trends – namely, improvements in psychological health and signals of change in cognitions for the intervention condition over control (data not shown – see Supplementary materials for model parameters, results, and side-by-side comparison of findings).

Exploratory longitudinal mediation analyses: Does mindfulness affect psychological health through health behaviour cognitions?

We conducted mediation analyses for all combinations of significant mediators at T2 (attitudes, social norms, PBC, behavioural intentions) and significant outcomes at T3 (wellbeing, depression, sleep quality). Given the exploratory nature of these analyses, we describe the findings to generate future hypotheses and not as conclusive findings.

Attitudes towards health behaviours and behavioural intentions to engage in them partially mediated the effect of condition (intervention vs. control) on all significant primary outcomes in simple models. Mediation was not detected through social norms nor perceived behavioural control. The mediating effect of attitudes was maintained when previous scores ("lags") were added into the models, whereas behavioural intentions did not maintain mediating indirect effects on in lagged models. All mediation models and additional details, including standard errors and exact *p*-values, are given in Supplementary materials.

Discussion

This pragmatic randomised controlled trial found that the digital, widely accessible mindfulness intervention Medito resulted in substantial improvements in psychological wellbeing, depression, anxiety and, over the longer term, sleep quality. Effects on wellbeing and depression were maintained at 2-month follow-up. We further observed an increase in theory-based health behaviour cognitions—namely more positive attitudes, greater perceived behavioural control, and stronger behavioural intentions to look after one's health, relative to active control. At follow-up, the intervention condition also reported greater autonomous self-regulation. Crucially, these cognitions mediated the effects on wellbeing and mental health: attitudes and behavioural intentions at post-intervention partially mediated the effects in simple mediation models, and for attitudes the mediating effects were maintained even after controlling for prior scores of mediators and outcomes. Our findings indicate that potential benefits of mindfulness meditation for psychological health i) can be achieved through accessible digital tools, and ii) may be driven by improved attitudes towards own health and behavioural intentions to maintain it.

The findings largely align with theories of mindfulness in behaviour change, which posit that the principles and practice of mindfulness facilitate behaviour change through improved self-regulation (i.e., umbrella term for a collection of processes comprising emotional and cognitive appraisal, attentional control, and self-related cognitions; Schuman-Olivier et al., 2020). Indeed, the present work detected more autonomous self-regulation—in the narrower sense of internal vs. external motivation—in the mindfulness group at follow-up, although we did not test this in our mediation models. This finding may be the first signal of a gradual shift in motivation to look after one's health, which is a key component of successful behaviour change interventions in the health domain (see Ntoumanis et al., 2021, for a review). Future longitudinal work is needed to confirm whether MBIs indeed produce favourable shifts in motivation, or whether our finding was a type I error. These conclusions also concur with more general models of self-regulation in illness and threat perception (Hagger & Orbell, 2022), which further explain the pathway from causal attributions and cognitive appraisal to behavioural responses. Moreover, our results add initial causal evidence to existing cross-sectional data showing that people with higher levels of mindfulness engage in more health-promoting behaviours (Sala et al., 2020)—at least via proxy measure of theoretical predictors—and report better health outcomes (Tomlinson et al., 2018).

Our data suggest that levels of barriers self-efficacy for looking after one's health were not changed by the intervention. While self-efficacy mediates behaviour change theoretically (Bandura, 1986) and in some empirical work (Schwarzer & Renner, 2000), its effects are often modest and overridden by practical constraints to enacting behaviour (e.g., access to facilities; Griffiths et al., 2007). Given that the scale used in this research focused in part on those practical barriers (e.g., "I believe that I could look after my health if my schedule conflicted with it"), which the mindfulness training intervention was unlikely to change, the results are understandable.

Having identified (some of) the mechanisms through which mindfulness training may improve psychological wellbeing and health, these constructs can be better targeted in future health behaviour change interventions or measured as mechanisms of action in future trials. Practical ways of implementation include optimisation of mindfulness content so it deliberately targets the mechanisms, or raising users' awareness of them, which could provide additional motivation for engagement or appeal to groups beyond those currently engaging with MBIs. The current trial only focused on general health behaviour-related constructs (e.g., health behaviour self-regulation), whereas it is likely that behaviour-specific constructs can also be supported through this mechanism (Gawande et al. 2019; Ruffault et al., 2016). For example, mindfulness interventions aiming to support physical activity behaviour could target (and measure) physical activity-related self-regulation to untangle the mechanisms of mindfulness further. Notably, we did not measure health behaviour engagement. Instead, we focused on health behaviour cognitions that precede them. The intention-behaviour gap is well-documented in health behaviour literature (Feil et al., 2023) and suggests that the mediating relationships may not be the same if behaviour itself were measured. Our work serves as a stepping stone towards research utilising objective measures of specific health behaviours (e.g., number of daily steps).

This remote RCT evaluation of a 'real-world', commercially available intervention provides insight into the uptake and use patterns of digital health tools across a global population. Access to objective app use data revealed that participants' engagement levels and fidelity varied a lot (data not shown – see Supplementary materials). This concurs with digital health behaviour change theories, which emphasise flexible design and usage patterns suited to individuals as most effective in the long-term (Ainsworth et al., 2017). It also underscores the need for facilitating engagement with interventions aiming to provide wellbeing support. Emphasising effective use would maximise the impact of tools designed for wide reach and accessibility, while maintaining effectiveness (Groot et al., 2022).

Our choice of an active control group increases confidence in the source of identified benefits to wellbeing and attitudes (i.e., mindfulness meditation training) and may even have masked some intervention effects. Trials with passive control groups tend to report more favourable findings towards intervention conditions, often due to placebo effects of participating in a trial (LaFave et al., 2019). Our control participants likely expected to practice and benefit from mindfulness meditation due to the nature of recruitment and accessing control content via the same mindfulness app as intervention condition, which could have induced some of the benefits they reported across time. Still, attention-matched controls are the gold standard in behavioural interventions (Aycock et al., 2018), with added complexity in the field of relaxation techniques (Ainsworth et al., 2019). Identifying appropriate active control interventions in MBI research is particularly challenging because of varied putative mechanisms of action (and corresponding control conditions; MacCoon et al., 2012). Our choice of audiobook excerpts aimed to control for time, attention and format of the intervention, as has been done previously (e.g., Polaski et al., 2021). Nevertheless, the specific audiobook we chose may have led to different participant experiences based on cultural relevance or interest, given our geographically diverse sample. Future research should explore cultural differences in response to active control conditions for MBIs and the precise mechanisms for which they control.

We observed a high attrition rate, which is reflective of real-world engagement on an as-needed basis (Huberty et al., 2019). It is also comparable to other entirely remote digital trials (Torous et al., 2020), and particularly characteristic of longitudinal program-evaluation studies, where each participant is not guaranteed compensation by contributing (Cohen & Schleider, 2022). Low retention can introduce an unknown amount of bias into our data, such as ‘survivor bias’, where participants observing change are motivated to stay engaged, whereas those not benefitting are lost to follow-up (e.g., Hughes & Tuller, 2022). In such datasets, results likely represent maximal rather than average effects, and should not be overstated (Fish et al., 2016). We attempted to guard against effects of attrition by sending weekly reminder emails to participants and pre-registering modified ITT analyses comparing scores at each timepoint separately via ANCOVAs, which avoided within-group comparisons of incomparable datasets across time. We were reassured to see that, while attrition between baseline and post-intervention was non-random, it was not dependent on condition allocation or baseline symptoms. Sensitivity analyses delivering comparable results of improved psychological health and initial changes in health behaviour cognitions provide further reassurance for our results despite incomplete data. Future digital trials could target retention even more explicitly, by exploring alternative remuneration options (Abshire et al., 2017), and using person-based co-participatory approaches (Yardley et al., 2015) that aim to optimise engagement in digital interventions. Despite attrition, the remote nature of our trial procedures proved efficient, facilitating recruitment of a large international sample in a relatively short time span of two months. This efficient method is likely to be cost-effective and environmentally conscious, while limiting the possibility for researcher bias or protocol deviation—a notable benefit in the sphere of behavioural interventions, where participant and researcher blinding is challenging (Ainsworth et al., 2019; Juul et al., 2021).

Our sample was more diverse (59.8% non-white) and had more male representation (61.7% male) than is the norm in mindfulness literature, where samples are predominantly white and female (Waldron et al., 2018). This was possibly due to recruitment via platforms with a larger male user base (such as YouTube; Statista, 2023) in addition to traditional digital recruitment. Our findings can inform future attempts to recruit, engage and support male and non-white participants in mental health research (NIHR, 2022). We did not collect data on socioeconomic indicators; however, our sample was likely still well-educated and affluent. Finding ways to gather more representation of non-WEIRD (Western, educated, individualist, rich, democratic; Henrich et al., 2010) populations is an avenue for future work. In addition, we studied a self-administered digital intervention, which could have precluded participation of groups with lower health literacy or those with no internet access (Proulx et al., 2018; Rad et al., 2018). This format may also have not been sufficiently intensive or engaging for some users (Fish et al., 2016), as suggested by our high attrition. The sample was self-selected, had low levels of mental health symptoms at baseline, and most participants downloaded the mobile application before entering the trial. This indicates that, while participants mostly had little experience with mindfulness meditation, they had an interest in it. Pre-existing interest may have strengthened the intervention effects and made them more likely to engage with the content—a possibility further reinforced by higher dropout rates among participants with less mindfulness experience. Yet, this recruitment and dropout pattern reflects the processes that occur in the real world when using scalable interventions in the general population, where mental health symptoms are generally below a clinical threshold (Sinclair et al., 2012). Any observed benefits to this type of sample may not replicate in clinical populations, although other work suggests that MBIs are a valuable approach for a range of clinical conditions (Jovanovic & Garfin, 2024; Sverre et al., 2023). Overall, studying broadly relevant and scalable digital tools is crucial to public health improvement strategies in increasingly digitalised prevention and treatment provision (WHO, 2021; HM Government, 2021). Cost-effective digital platforms promote equitable access to health information and support, helping to narrow the digital health divide (Makri, 2019; Western, 2022; Western et al., 2021).

Finally, our study of a self-delivered MBI adds to the substantial literature base on the effectiveness of mindfulness-based approaches for improvements in mental health (Hofmann et al., 2010). While valuable, research suggests that MBIs and other third-wave therapies are not universally appropriate (e.g., MBIs have been associated with transient anxiety; Aizik-Reebs et al., 2021) nor effective (as was found recently in a large-scale trial of UK adolescents; Montero-Marin et al, 2022). Therefore, interventions such as the one tested here should be seen as one of the possible tools available to the general population at scale, rather than a universal approach recommended without consideration of the needs of each individual group.

Conclusion

The present pragmatic RCT of an accessible digital mindfulness-based intervention observed improvements in psychological wellbeing and mental health in a large, diverse, international sample. These changes may be mediated by health cognitions that precede engagement in health behaviour, including attitudes, behavioural intentions and gradual shifts in self-regulation. This work advances current understanding of mechanisms of action in mindfulness-based interventions, enabling future work to target more specific health behaviours and measure effects on tangible behaviours.

Table 1. Participant demographics and baseline measures for intervention and control groups.

Measure	Intervention (N = 618)	Control (N = 629)
Age, M (SD)[a]	27.3 (10.5)	26.8 (9.2)
Gender (%)	Female (34%)	Female (37%)
	Male (64%)	Male (59%)
	Other (2%)	Other (3%)
Ethnicity (%)	Asian (42%)	Asian (40%)
	Black (3%)	Black (4%)
	White (39%)	White (41%)
	Mixed (6%)	Mixed (6%)
	Other (10%)	Other (9%)
Meditation experience (%)	None (28%)	None (27%)
	Limited (34%)	Limited (38%)
	Some (20%)	Some (20%)
	Moderate (15%)	Moderate (12%)
	Abundant (3%)	Abundant (3%)
WEMWBS	40.56 (8.73)	39.98 (8.74)
DASS-21		
Depression	8.90 (4.98)	9.24 (5.16)
Anxiety	6.71 (4.43)	6.73 (4.43)
Stress	9.60 (4.37)	9.97 (4.37)
Sleep quality	5.70 (1.90)	5.63 (1.93)
TSRQ		
Autonomous SR	5.31 (1.38)	5.27 (1.38)
Controlled SR	3.13 (1.33)	3.22 (1.37)
RAI of SR	2.16 (1.73)	2.03 (1.72)
BARSE	3.40 (1.35)	3.52 (1.37)
TPBQ		
Attitudes	5.60 (1.43)	5.62 (1.39)
Social norms	3.68 (1.71)	3.91 (1.79)
PBC	5.25 (1.53)	5.22 (1.45)
Behavioural intentions	5.75 (1.42)	5.72 (1.39)

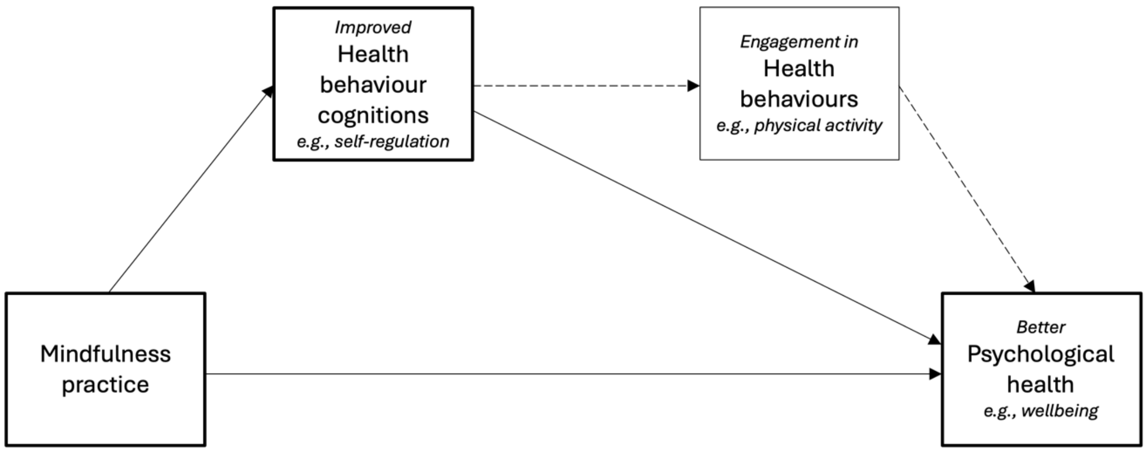
Notes: WEMWBS – Warwick-Wdinburgh Mental Well-Being Scale (range 0-70, where higher scores indicate better wellbeing). DASS-21 – Depression, Anxiety and Stress Scales short form (range 0-21 for each subscale, where higher scores indicate more severe symptoms). TSRQ – Treatment Self-Regulation Questionnaire (range 0-7 for either subscale, where higher scores indicate greater presence of the type of motivation; RAI range -7-7, where positive scores indicate a more autonomous balance of motivation and negative more controlled balance of motivation). BARSE – Barriers Self Efficacy Scale (range 0-7, where higher scores indicate greater self-efficacy). TPBQ – Theory of Planned Behaviour Questionnaire (range 0-7 for each subscale, where higher score indicate stronger behavioural predictors). Values may not add up to 100% due to rounding.

Table 2. Baseline, post-intervention and follow-up outcome measures of randomised intervention and control participants.

Primary outcomes	Intervention (M, SD)			Control (M, SD)			Intervention vs. Control Comparison (M, 95% CI)	
	Baseline (N = 618)	Post-intervention (N = 155)	Follow-up (N = 80)	Baseline (N = 629)	Post-intervention (N = 145)	Follow-up (N = 83)	Post-intervention (T2)	Follow-up (T3)
Wellbeing (WEMWBS)	40.56 (8.73)	50.43 (9.33)	51.61 (9.06)	39.98 (8.74)	46.95 (9.54)	47.88 (10.91)	2.34 (0.45, 4.24)*	3.06 (0.25, 5.87)*
Depression (DASS-21)	8.90 (498)	4.49 (4.53)	3.76 (3.91)	9.24 (5.16)	6.43 (5.04)	6.04 (5.42)	-1.47 (-2.38, -0.56)**	-1.86 (-3.17, -0.54)**
Anxiety (DASS-21)	6.71 (4.43)	4.28 (3.83)	3.54 (3.31)	6.74 (4.43)	5.15 (4.15)	3.95 (3.94)	-0.77 (-1.51, -0.02)*	-0.56 (-1.45, 0.34)
Stress (DASS-21)	9.60 (4.37)	6.44 (4.18)	5.76 (3.68)	9.97 (4.37)	7.13 (4.34)	6.52 (4.24)	-0.57 (-1.47, 0.32)	-0.88 (-2.04, 0.28)
Sleep quality (VAS)	5.70 (1.90)	7.16 (1.80)	7.49 (1.64)	5.63 (1.93)	6.88 (1.74)	6.76 (2.10)	0.19 (-0.19, 0.58)	0.68 (0.17, 1.19)*
Secondary outcomes	Baseline	Post-intervention	Follow-up	Baseline	Post-intervention	Follow-up	Post-intervention (T2)	Follow-up (T3)
Autonomous SR (TSRQ)	5.31 (1.38)	5.75 (1.21)	5.85 (1.15)	5.27 (1.38)	5.52 (1.32)	5.46 (1..43)	0.15 (-.09, 0.39)	0.33 (0.02, 0.64)*
Controlled SR (TSRQ)	3.13 (1.33)	2.83 (1.50)	3.02 (1.51)	3.22 (1.37)	3.22 (1.57)	3.23 (1.54)	-0.17 (-0.47, 0.14)	-0.03 (-0.41, 0.35)
SR index (TSRQ RAI)	2.16 (1.73)	2.94 (1.86)	2.83 (1.62)	2.03 (1.72)	2.29 (1.99)	2.24 (1.99)	0.27 (-0.10, 0.63)	0.42 (-0.08, 0.91)
Self-efficacy (BARSE)	3.40 (1.35)	3.86 (1.51)	3.89 (1.29)	3.52 (1.37)	3.80 (1.29)	3.64 (1.39)	0.15 (-0.19, 0.48)	0.28 (-0.13, 0.69)
Attitudes (TPBQ)	5.60 (1.43)	6.06 (1.30)	6.11 (1.20)	5.62 (1.39)	5.68 (1.36)	5.77 (1.40)	0.33 (0.08, 0.57)*	0.37 (0.04, 0.71)*
Social norms (TPBQ)	3.68 (1.71)	3.28 (1.86)	3.36 (1.79)	3.91 (1.79)	3.97 (1.59)	3.73 (1.83)	-0.59 (-0.95, -0.22)**	-0.37 (-0.83, 0.10)
PBC (TPBQ)	5.25 (1.53)	5.92 (1.13)	5.82 (1.37)	5.22 (1.45)	5.58 (1.26)	5.49 (1.49)	0.21 (0.01, 0.42)*	0.26 (-0.10, 0.61)
Behavioural intention (TPBQ)	5.75 (1.42)	6.14 (1.09)	6.08 (1.35)	5.72 (1.41)	5.74 (1.40)	5.72 (1.39)	0.26 (0.03, 0.50)*	0.21 (-0.12, 0.54)

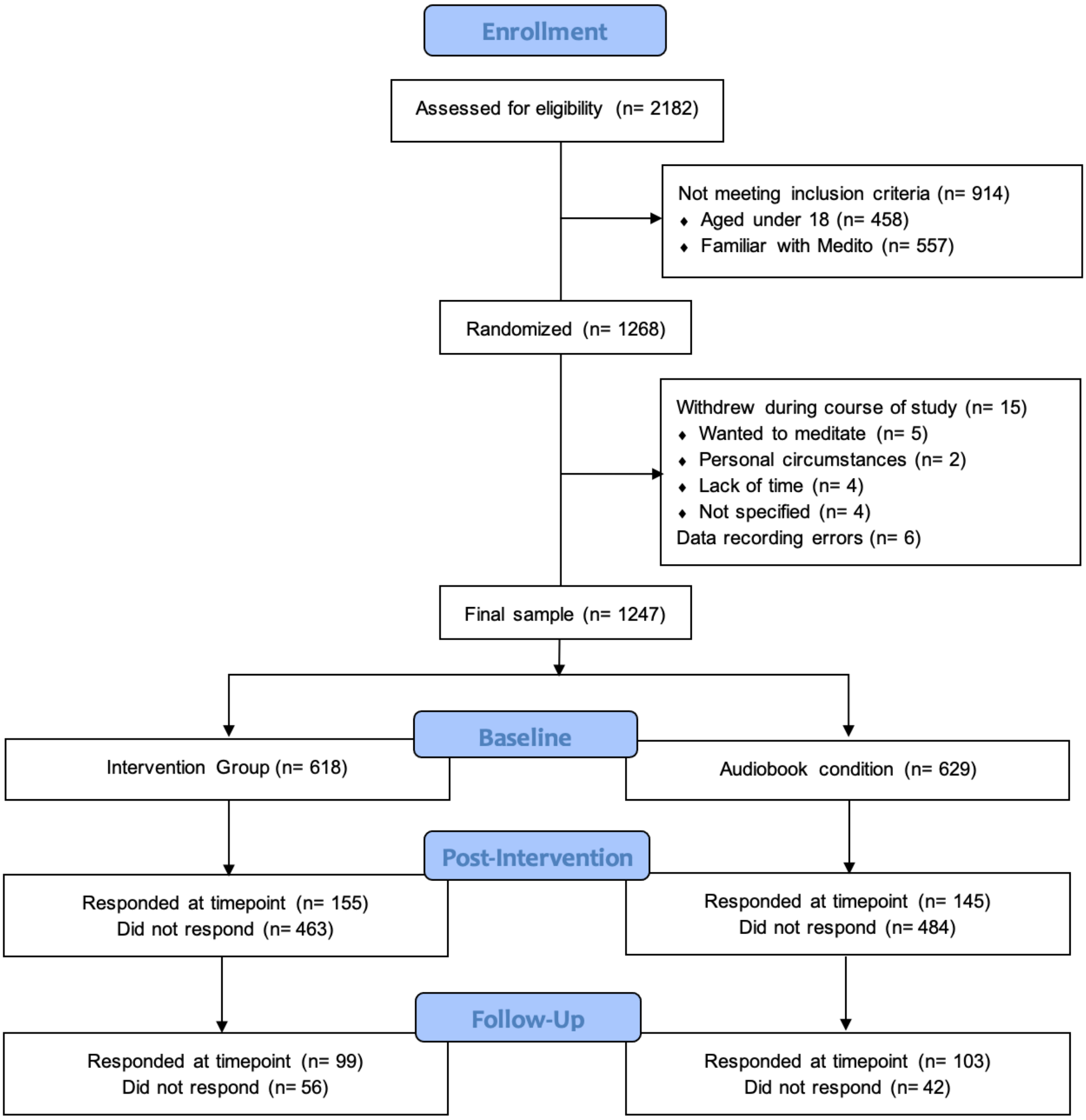
Note. Between-group differences are reported as estimated marginal mean difference scores (corrected for baseline values of each measure). Missing data were not imputed and data presented here represent a modified intention-to-treat analysis, where participants are analysed as randomised if they provided data at T2 and T3. (*) indicates a between-group difference where $p < .05$. (**) indicates a between-group difference where $p < .01$.

Figure 1. Proposed process model demonstrating the path through which MBIs may improve engagement in health behaviours and psychological health outcomes. Drawing on Schuman-Olivier et al. (2020) and Hagger & Orbell (2022).



Note. Full lines and bold box outlines represent the path model tested in this work. Dotted line represents an avenue for future work.

Figure 2. CONSORT diagram of recruitment and retention during the trial.



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