Title: Internet-based Mindfulness-based Training (iMBT) for People with Depression: Investigation of its efficacy and mechanism of change
NCT number: SBRE-21-0158
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THE CHINESE UNIVERSITY OF HONG KONG

Survey and Behavioural Research Ethics

Application Form

NOTE: This Form is to be completed by researchers whose research studies involve survey or observation on human subjects. Please read the ***Guidelines for Survey and Behavioural Research Ethics*** carefully before completing this Form. Once the Form is completed, please submit together with all relevant documents to the *Survey and Behavioural Research Ethics Faculty Sub-committee* (c/o Faculty Office concerned). With all the necessary information and documents received, the processing time of each application is approximately 6 to 8 weeks from the time of application.

[For SBREC Use Only]		
Reference No.	:	
Date of Received	:	
Type of Review	:	☐ Expedited
		☐ Full

Part A: Basic Information

Project Title

Internet-based Mindfulness-based Training (iMBT) for People with Depression: Investigation of its efficacy and mechanism of change

Name of Grant Applied /Being Applied *(if applicable)*	**Grant Ref. No. / Account No.** *(if applicable)*
Name of Principal Investigator *(Please underline the surname)(in full)* Winnie W.S. Mak	**Department / Unit** *(in full)* Psychology
Tel. No. 39436577	**E-mail Address** wwsmak@cuhk.edu.hk

For students	**Name of Supervisor / Course Instructor**	**Programme and Year of Study**	**Student ID**

Certification of Ethics Training Test(s)

For details, please visit the Research Ethics Training Website (https://www.research-ethics.cuhk.edu.hk/web/)

	E-Cert ID	**E-Cert End Date**
1. Survey and Behavioural Research Ethics	B106610	27/01/2022
2. Publication Ethics	B106610	27/01/2022

Part B: Summary of Research Proposal *(maximum 150 words)*
Summarize, in layperson's language, the objective(s) and significance of the research.

Major depressive disorder is a significant public health concern, and internet-based psychotherapy is a promising therapeutic approach. With growing evidence that mindfulness-based interventions are efficacious in treating depression, this research seeks to examine whether internet-based mindfulness-based therapy (iMBT) is similarly effective. The aims of this study are:
(1) to evaluate the efficacy of iMBT in treating adults with depression as compared to usual care, and
(2) to investigate the mechanisms of iMBT with various statistical tools.

If validated, this research can provide support for the clinical utility of iMBT as a stand-alone mental health intervention for people who are clinically depressed. This study will advance our understanding of the causal pathways between mindfulness-based intervention and depression and guide future research, theoretical developments and clinical practice. This effort increases our repertoire of treatment offerings for people with depression.

Part C: Particulars of Research

Human participants

Age range *(Check all that apply)* ☐ 0-17 ☒ 18-59 ☒ 60+

Specification of the inclusion and exclusion criteria of the study *(if any)*

For inclusion, participants must be (1) over 18, (2) have access to computer and mobile phone (since this is an internet-based therapy), and must (3) score >9 on PHQ9, (4) have ability to read and type Chinese. Exclusion criteria includes (1) self-reported presence of psychosis or bipolar disorder, post-traumatic stress disorder, drug or alcohol dependence, current use of antipsychotic medications, (2) self-reported frequent suicidal ideation (more than half of the days in the past two weeks), (3) completion of an online mental health program/research for depression in the past 3 months

1. Does the study use **only** publicly available data? ☐ Yes ☒ No

2. Does the study involve **only** survey or observation of public officials? ☐ Yes ☒ No

If you have checked "Yes" to any of the above questions, you can skip Question 3 and go straight to Question 4 to apply for an expedited review.

3. Checklist to determine whether a full review is needed:
   (a) Does the study involve participants who are unable to give informed consent (e.g. children, individuals with intellectual disabilities or cognitive impairments)? ☐ Yes ☒ No

   (If Yes, please elaborate how consent can be obtained in Question 4.)

   (b) Will deception of participants be necessary prior to or during the study? *(If Yes, please attach a debriefing form.)* ☐ Yes ☒ No

   (c) Details on participant remuneration:
      (i) Will participants receive inducements or rewards (other than reasonable expenses and compensation for time) before, during, or after participation? ☒ Yes ☐ No

      If Yes, please specify the form of remuneration e.g. cash, course credit, gift certificate. For cash and gift, state the amount; for course credit, state its percentage of the final grade:

      Participants can get a maximum of $200 (either cash or gift certificate) to compensate for time used to complete the assessments.

      (ii) Will the payment be prorated for partial participation? ☐ Yes ☒ No

(d) Does the study involve sensitive aspects of the participant's own behaviour such as illegal conduct, illicit drug use, suicidality, and sexual conduct? *(If Yes, please provide details in Question 4.)* ☐ Yes ☒ No

(e) If the observations on the participants are disclosed, will it reasonably place the participant at risk of criminal or civil liability or be damaging to the participant's financial standing, employability, or reputation? ☐ Yes ☒ No

If Yes, please provide details below:

(f) Does the study/experiment induce undue psychological stress? ☐ Yes ☒ No

If Yes, please provide details below:

(g) Is pain or more than mild discomfort likely to result from participating the study? ☐ Yes ☒ No

If Yes, please provide details below:

(h) Does the study involve prolonged and repetitive testing? ☒ Yes ☐ No

If Yes, please provide details below:
Participants will be expected to complete an Internet-based mindfulness-based training delivered over a 6-week period via an internet e-learning mental health platform.
Participants will be assessed at four different time points:
(1) before intervention (T0), (2) 2,4 weeks since the commencement of group (T1,2), (3) 6 weeks after (i.e., when the intervention ends) (T3), (4) at 3-month follow-up(T4).

(i) Will the participants be identified? ☐ Yes ☒ No

If Yes, please provide details below:

If you have checked "Yes" to any of the above items, you must go through a full review. Please attach a detailed research proposal.

4. Summary of Research Procedures *(maximum 300 words)*
Describe what the participants will do, where the research activities will take place, the total number of sessions the participants need to participate and their total time commitment. Besides, please attach the instruments (e.g. questionnaire, focus group discussion guide, interview guide, etc.) that will be used in data collection. If the instruments are not yet available, please provide a detailed description of them.

Participants who have provided consent and passed an online screening (based on the above-mentioned inclusion and exclusion criteria) will engage in a 6-week IMBT, consisting of 6 modules with 4 sections each. It is expected that participants will complete one module per week, each module lasting around 1 hour while participants are encouraged to practice for 15 minutes a day.
The control group will be advised to seek assistance from their usual healthcare provider when needed.
Both treatment group and control group will be assessed at four different time points:

before intervention (T0), (2) 2,4 weeks since the commencement of group (T1,2), (3) 6 weeks after (i.e., when the intervention ends) (T3), (4) at 3-month follow-up(T4).
Initial screening will utilise the PHQ9. Once participants have been recruited, online assessments will be conducted via Qualtrics at each of the aforementioned timepoints. The assessments will include:

- Patient Health Questionnaire (PHQ9)
- Five Facets Mindfulness Questionnaire – Short form (FFMQ-SF)
- Warwick Edinburgh Mental Wellbeing Scale
- Credibility and Expectancy Questionnaire (CEQ)
- Difficulties in Emotional Regulation Scale (DERS)
- Nonattachment scale
- Stillness scale
- Equanimity scale
- Peace of mind scale

5. Will consent form be used? ☒ Yes ☐ No

If No, please provide reason(s) below:

(a) Type of consent *(Check all that apply)(Please attach a copy of consent form.)*

☒ Formal Consent

- ☒ Informed consent
  (for participants able to give legal valid informed consent and not belonging to any vulnerable groups)
- ☐ Parent/guardian consent
  (for participants under 18 years old or those belonging to a vulnerable group)
- ☐ Assent form
  (for participants not competent to give legal valid informed consent)
- ☐ Passive informed consent
  (for surveys to be conducted through the schools or other authorities)

☐ Informal Consent

Please provide justifications:

6. Confidentiality of data

(a) Collection of auditory and visual data *(Check all that apply)*

☐ Audiotapes ☐ Still photos
☐ Videotapes ☒ Not applicable

(b) Does the study involve multi-phase data collection? ☒ Yes ☐ No

If Yes, please explain the tracking and coding system(s):

Participants will be identified by a unique ID to match their data across time.

(c) Does the study involve collecting data through an Internet survey platform? ☒ Yes ☐ No

If Yes, please address the confidentiality of data collected via e-mail, Web interfaces, and other networked information: Yes, Qualtrics will be used, participants again identified by their respective unique IDs.

(d) Will any individually identifiable information, including images of participants, be published, shared, or disseminated? ☐ Yes ☒ No

If Yes, please elaborate how the explicit consent or assent for such publication/share/dissemination can be obtained from participants:

7. Data Security

Describe how and where data will be kept to protect participant's confidentiality.

Appendix 1 – Grant Application

THE CHINESE UNIVERSITY OF HONG KONG
Social Science Panel

Application no. : _____ (For Office Use Only)

Direct Grant for Research 2019-20
Application Form

1. Investigator(s) Information
[Please attach a CV (within two A4 pages) for the Principal Investigator and each Co-Investigator (if any).]

	Name	Department / Unit
a) Principal Investigator	Winnie W. S. Mak	Psychology
b) Co-Investigator(s)	Larry Auyeung	Psychology

2. Plan to develop this proposal into RGC General Research Fund (GRF) / Early Career Scheme (ECS) proposal within two years :

☑ Yes (for applied amount up to HK$100,000)
☐ No (for applied amount up to HK$50,000) *(Please skip part 4a)*

3. Project Title

Internet-based Mindfulness-based Training (iMBT) for People with Depression: Investigation of its efficacy and mechanism of change

4. Project Objectives and Long-term Significance *(A maximum of one A4 page)*

Please state the purpose of the proposed investigation, identify the key issues and problems being addressed and the possible outcome of the research project, its relevance, significance and value.

Project Objectives

Major depressive disorder is a significant public health concern due to its high prevalence, high disease burden, and common comorbidity. One promising approach to enhance the accessibility and serviceability of psychotherapy is to complement the existing health system through evidence-based self-management programs delivered via the Internet. Despite the growing evidence of the efficacy of mindfulness-based interventions in the treatment of an array of physical health and mental health conditions, research into the efficacy of Internet-based mindfulness programs and its therapeutic mechanism on the treatment of common mental disorders is relatively scarce. Through the development of Internet-based mindfulness-based training (iMBT) and close examination of its mechanisms, detailed refinement in the program development can be made to maximize its effectiveness for specific populations.

With reference to the current research and service gap, our aims of this study are:

(1) to evaluate the efficacy of iMBT in treating adults with depression as compared to usual care, and

(2) to investigate the mechanisms of iMBT using latent growth curve modelling

We expect that the newly developed iMBT will have favorable effect on depressive symptoms, mindfulness, difficulties in emotion regulation, and positive mental well-being among adults with depression.

Long-term Significance

Practically, given the popularity of mindfulness and wide-spread adoption of e-therapy, this research can provide support for the clinical utility of iMBT as a stand-alone mental health intervention for people who are clinically depressed. Theoretically, this study will advance our understanding of the causal pathways between mindfulness-based intervention and depression and guide future research, theoretical developments and clinical practice. This effort increases our repertoire of treatment offerings for people with depression. Especially, in light of the long waiting time in the public mental health services, the expansion of evidence-based online interventions provide an effective and efficient way for individuals with varied mental health needs to obtain the interventions the need. By systematically testing iMBT as possible treatment of choice for people with depression, we add to the offerings of Internet-based interventions as expand the use of iMBT to not only for mental health promotion and mental illness prevention, but also treatment for depression.

In addition to establishing its effectiveness in the treatment of depression, by dismantling the process by which iMBT lead to changes in individuals' approach to life and subsequent improvement in their mental well-being, we can further deliberate how to adapt iMBT to increase awareness and maximize gains. This proposal is one of the series of attempts in my research lab that aims to build a wide repertoire of online programs and services with the aims to improve public mental health. The building of a versatile iMBT portal in this application through Learning Management System would allow our team to continue to conduct research on online interventions with the aims to develop personalized public mental health.

How will this proposal be developed into RGC General Research Fund (GRF) / Early Career Scheme (ECS) proposal? *(A maximum of one A4 page)*

If iMBT is showed to be effective in the treatment of people with depression, our next step is to conduct a non-inferiority trial comparing iMBT with Internet-based cognitive behavioral therapy (iCBT) in the treatment of common mental disorders. The reason for this progression being iCBT is a well-established intervention for the treatment of depression and anxiety. A recent meta-analytic review showed that iCBT was as effective as its face-to-face counterpart for clinical practice in treating depression[16]. If iMBT is demonstrated to be as effective as iCBT in the non-inferiority trial, we have the potential to increase our repertoire of mental health services and approaches to the general public for the treatment of common mental disorders. So far, no study has compared these two streams of intervention approaches, especially online interventions. Moreover, with this step, we will be in greater position to identify moderators that help us determine which interventions are suitable for whom under what kind of circumstances. This question is essential in the development of personalized mental health care.

In subsequent grant proposal, we aim to further dissect and unpack the active ingredients in iMBT and iCBT that allows us to make more precise prediction for individuals' outcomes. With more data being collected, we also aim to leverage machine learning and big data analytics to observe patterns that allow us to refine our approaches for based on individuals' psychosocial profiles. Under implementation science, our aim is to understand how best to implement different online and low-intensity approaches by investigating on usage patterns, adherence factors, specific features of each program, and match between person's preferences with program's offerings.

5. Background of Research *(A maximum of three A4 pages, including references.)*

Summary of related work already done by you and other researchers, and outline of previous and alternative approaches to the issue:

1.1 Internet delivered Intervention for Depression

Major depressive disorder (MDD) is a significant and common public health concern due to its high prevalence, high disease burden, and common comorbidity [1–3]. While evidence-based psychological treatments are available, most of those affected by depression do not have access to these treatments or seek help[5]. Several reasons such as long waiting time of mental health service, barriers in access to care, and reluctance to seek help due to stigma are contributing to this situation[6]. One promising approach to enhance the accessibility and serviceability of psychotherapy is to complement the existing system using evidence-based self-management programs delivered via the Internet. Different forms of psychotherapy, could potentially be transferable to

Internet-based interventions, especially when guided by coaches[9] who provide online guidance, encouragement, and therapeutic activities [10,11]. The initiatives of translating and scaling up mental health service via the Internet echo with the National Institute for Health and Care Excellence guidelines (NICE) for managing depression [12]. The guideline recommended low-intensity Internet-based interventions as first line treatment prior to more complex higher-tier services. Internet-based interventions for major depression has not only been shown to be efficacious [13], but also cost-effective and able to generate societal savings[14,15]. Notably, a recent meta-analytic review revealed that Internet-based cognitive behavioral therapy (iCBT) was as effective as its face-to-face counterpart for clinical practice in treating depression[16]. Given the high accessibility and low recurring costs of Internet-based interventions for depression, these interventions are suggested to have a huge potential for public mental health impact.

1.2 Mindfulness-based Training as an Internet delivered Intervention for People with Depression

In addition to iCBT, Internet-based mindfulness-based training (iMBT) has also gained evidence in improving mental well-being and reducing psychological distress. Mindfulness is defined "paying attention in a particular way: on purpose, in the present moment, and nonjudgmentally" [17,18]. In the context of understanding the beneficial effect of mindfulness on depression, it is theorized that mindfulness training reduced depression through encouraging individuals to notice experiences regardless of its valence labelled, and to approach those experiences with gentleness, curiosity and interest without suppressing, judging, or pushing these experiences away [19]. In turn, repetitive negative thinking, which involves cognitive over-engagement in attempt to control unpleasant inner experiences, would be attenuated by the facilitation of individuals' processing of their affective experiences[17,20]. Moreover, through observing that different experiences come and go over time, mindfulness practitioners come to know the impermanent and transitory nature of the inner experience and realize that it is not always necessary to react.

A recent meta-analysis that included 209 studies with 12,145 participants concluded that mindfulness-based intervention is an effective treatment for various psychological problems, and is especially effective for reducing depression, anxiety and stress[21]. Evidence of online mindfulness-based intervention has demonstrated its effectiveness among community samples and subclinical populations with elevated depressive symtoms[23,24]. In addition, iMBT may be more acceptable than intervention using the traditional cognitive behavioral approach. As reported in a recent study, intervention with mindfulness element was chosen as the first option of intervention by over 80% of people with depression/anxiety. Moreover, nearly half of the participants in a study reported preference of online formats for mindfulness interventions over group/individual formats[28].

Given its acceptability and preference by individuals with mental health needs and its promising effects in reducing depressive and anxiety symptoms, another critical question lies in examining how MBT works so that further refinement of such approach can be made based on its theoretical roots and mechanism of change. The precise mechanisms underlying the effect of mindfulness have received recent theoretical attention[19,29,30]. Despite not having abundant studies, recent meta-analysis of mediation studies with 12 RCTs identified consistent evidence for the change in mindfulness as a mechanism underlying MBIs[31]. However, simply identifying mindfulness as the mechanism of change in MBT is too crude and intuitive. Further unpacking the effects of mindfulness is necessary to understand the process through which individuals experience changes. One possibility is to examine specific effect of each facet in mindfulness (i.e., observe, describe, act with awareness, non-react and non-judgement). Correlational study suggested that different facets of mindfulness have differential relationships with various psychological variables [32]. Although most facets of mindfulness are frequently found to be associated with reduced psychological distress, the "observe" facets is often uncorrelated or even positively correlated with mood symptoms [33]. In accord with the Acceptance and Monitor theory[19], a recent study showed high observing skills was correlated with higher depressive symptoms with low acceptance. Yet, high observing skills in combination with high acceptance correlated with increased adaptive cognitive processing tendencies [34]. Consequently, it is important to examine relationships between change of mindfulness and that of psychological symptoms at the facet level to provide a more fine-grained perspective on the contribution of mindfulness. This could also facilitate refinement of iMBT.

1.3 Aims and hypotheses

The research goals of this randomized controlled trial are to determine the feasibility and the mechanism of change of iMBT that has been developed using the Acceptance Checklist for Clinical Effectiveness Pilot Trials (ACCEPT) framework[35].

The primary research question is as follows:

- What is the effectiveness of the iMBT in relation to improvements on depressive symptoms among people with clinical depression, relative to a usual care control after the intervention and in 3-month follow-up?

Secondary questions include the following:

- Which facet(s) of mindfulness (i.e., observe, describe, act with awareness, non-react and non-judgement) improved during the intervention?

- How does the growth trajectory of different facets of mindfulness relate to the improvement of well-being and reduction of ill-being?

We hypothesize that:

H1 Participants in iMBT group will have greater reduction in depressive symptoms and increase in all facets of mindfulness and mental well-being, than the usual care group at post-intervention, and 3-month follow-up.

H2 Using latent growth analysis, the intraindividual growth trajectory of the monitor and acceptance facets of mindfulness would mediate the effect of iMBT on the intraindividual changes in depressive symptoms.

H3 Using multi-group analysis, in accord with Acceptance and Monitor theory, the relationship between the growth trajectory of monitor facets of mindfulness and the growth trajectory of depressive symptoms will be moderated by the level of acceptance. People with greater acceptance of inner experience will benefit more from the change of monitor facets of mindfulness in iMBT.

References

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6. Research Plan and Methodology *(A maximum of three A4 pages, including key references.)*

2 Research Plan and Methodology

2.1 Trial design, Procedure and Study Flow

A two-armed parallel RCT following CONSORT statement[1] will be conducted to examine the efficacy of an Internet-based mindfulness-based training (iMBT) to a treatment-as-usual control group (TAU). Intervention (iMBT) will be delivered over a 6-week period via an internet e-learning mental health platform.

All participants who are interested to join this research will be provided with an electronic informed consent form, and online screening. The online screening included a self-assessment of depressive symptoms using PHQ-9 as well as items that assessed the inclusion and exclusion criteria.

Participants will be included if they are: (1) aged over 18, (2) have access to computer and mobile phone, (3) scored > 9 on PHQ-9, administered via telephone by trained interviewers, and (4) have ability to read and type Chinese. Exclusion criteria includes (1) self-reported presence of psychosis or bipolar disorder, post-traumatic stress disorder, drug or alcohol dependence, current use of antipsychotic medications, (2) self-reported frequent suicidal ideation (more than half of the days in the past two weeks), (3) completion of an online mental health program/research for depression in the past 3 months.

Any excluded applicants will receive contact information on community mental health services. Following telephone assessment, eligible participants will be randomized to either iMBT or TAU by block randomization with block number of 6 with allocation ratio of 1:1.

Participants will be assessed at the following time points: (1) before intervention (T0), (2) 2,4 weeks since the commencement of group (T1,2), (3) 6 weeks after (i.e., when the intervention ends) (T3), (4) at 3-month follow-up(T4). Participants in the TAU will have the assessment according to specific times as the iMBT group (i.e. weeks since commencement of group) (see Figure 1).

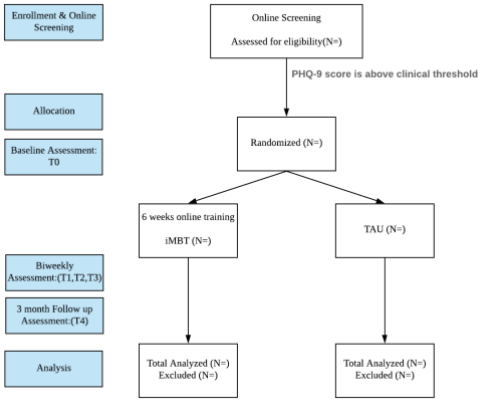

Figure 1 CONSORT flow diagram

2.2 Intervention

2.2.1 Internet-delivered Mindfulness Based Training (iMBT)

The iMBT developed for this study will be adapted from our team's previous study[3] and the manual of mindfulness based cognitive therapy[4]. To suit a public mental health approach and to increase program attractiveness and adherence, the program is designed to be brief in nature while strive to preserve all the essential elements in the original manual and program, for example, participants will be asked to practice meditations for 15 minutes a day instead of the original 45 minutes a day, and each module is shortened to approximately 1 hour instead of the original 2.5 hours.

The core focus of iMBT will be on educating participants to adopt a new way of being and relating to their thoughts and feelings, and altering specific cognitions is not emphasized. This iMBT is comprised of six weekly modules on education about mindfulness, guidance on using mindfulness skills to manage symptoms, guided meditations (e.g., mindful breathing, mindful eating, mindful walking, body scan, acceptance, choiceless awareness and disengaging from thoughts exercise), and guidance on using informal mindfulness skills in day-to-day life.

Readings, audio and graphics are included to explain the concept of mindfulness and overcome common difficulties associated with mindfulness practice. Furthermore, participants are encouraged to practice daily mindfulness exercises using the downloadable audio built within the learning platform. Participants will reflect on their experiences by keeping a personal log. An online coach, who will be a trained undergraduate student in psychology, will give weekly written feedback based on this log through a secured e-mail system, guiding the participants through the program with personal feedback, encouragement and support.

2.2.2 Treatment-as-usual control group (TAU)

The TAU group will be advised to seek assistance from their usual healthcare provider when needed.

2.3 Power Calculation and Sample Size

Based on past research[5], we expected a small to medium (f = 0.11) difference between the iMBT and the TAU control group. Thus, using G ∗ Power software (version 3.1.9.2), a sample size of 116 will be needed to detect superiority of the intervention groups over the TAU control group with 80% power.

2.4 Analytical procedure

2.4.1 Efficacy analyses of iMBT on Depressive symptoms, Mindfulness, and Mental Well-being

Significance testing of baseline group equivalence will be conducted using Analysis of variance (ANOVA) and chi square test if the variables consisted of nominal data.

To investigate the efficacy of iMBT, intention-to-treat (ITT) linear mixed models using restricted maximum likelihood (REML) estimation will be conducted for each outcome measure.

Fixed factors of time, group, and time*group will be entered in each model. Within-group effect size will be computed for pre(T0)-to-post(T3), and pre(T0) to follow-up(T4) changes on each outcome measures, and between-group effect sizes (Hedge's g) will be computed at post(T3) and follow-up(T4). Reliable change scores were calculated [6] between pre(T0)and post(T3)-intervention, as well as between pre(T0)and follow-up(T4) for the PHQ-9, to determine rates of clinically reliable improvement and deterioration. All analyses will be performed in SPSS version 24.

2.4.2 Mechanism of the iMBT: Parallel process growth modelling

To investigate which facet(s) of mindfulness mediate(s) the therapeutic effect of iMBT, parallel process growth modelling will be used. Structural equation modelling (AMOS, version 26.0) will be used to compute the latent growth curve models [7,8]. Latent growth curve modelling is a longitudinal analysis that analyzes growth over a period of time. Each growth curve has a latent baseline (the intercept) and a growth rate over time (the slope). LGM here will be used to characterize the overall trajectories of change (slope) of all five facets in mindfulness. How changes in each facets of mindfulness covaries between conditions, and the extent to which changes in each facets of mindfulness **(**putative mediators) mediates the effects of iMBT on changes in mental health outcomes will be analyzed. Quadratic growth factors will be added to the models to better estimate the trajectory shape when necessary.

To assess the existence of a mediating indirect effect from intervention allocation to the mental health outcome via the putative mediators, we will combine the growth model for the metal health outcome and the growth model for each putative mediators model into a combined parallel process growth model (see Fig 2). We will test the product of (a) the effect of treatment allocation on the growth of the mediator and (b) the effect of growth on the mediator on the growth rate on the outcome. The ab-product's confidence intervals will be estimated based on bootstrapping of 1000 samples[9].

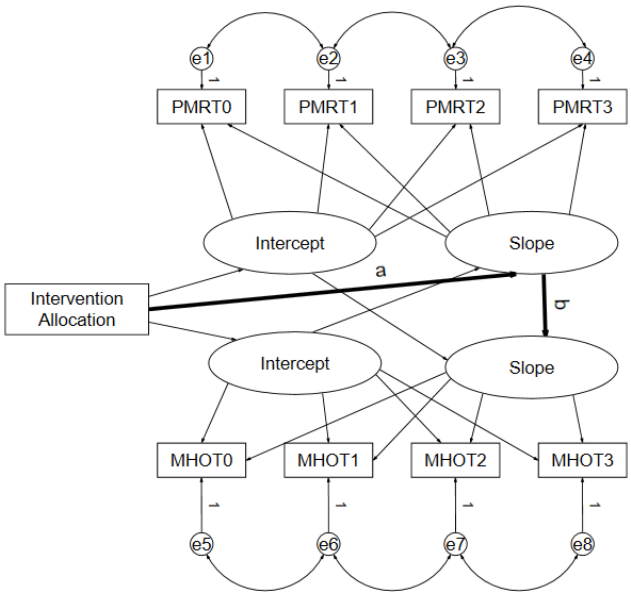

Figure 2. Parallel process growth model to assess statistical mediation over slopes. Rectangles denote observed variables and ellipses denote for latent variables. PMR = putative mediator (i.e. five facets in mindfulness which include observe, describe, act with awareness, non-react and non-judgement) MHO= mental health outcome (i.e. depressive symptoms, well-being, and difficulties in emotion regulation) T0,T1,T2 and T3 = Assessment at week 0,2,4 and 6. Bolded arrows highlighted the path of primary interest, which include the path from treatment allocation, (a)to growth in the putative mediator, to growth in the mental health outcome (i.e., the ab-product).

The adequacy of the models will be examined the following goodness of fit indices: comparative fit index (CFI), Tucker and Lewis index (TLI), and incremental fit index (IFI), which indicate a good adjustment to empirical data when around 0.95, and the standardized root mean squared residual (SRMR), which indicates a good adjustment when <0.08 [10].

2.5 Feasibility

Given that our laboratory has already developed the prototype of the iMBT, it is anticipated that this trial will be completed within a 2-year period, with approximately 70% of participants retained. This is in line with

similar e-psychotherapy studies where one meta-analysis reported an average of 23% dropout.

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7. Working Schedule

a) Start Date: June 30, 2020 (DD/MM/YYYY)

b) End Date: June 29, 2022 (DD/MM/YYYY)

c) Duration (in months): 24 months

Signature of Principal Investigator

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Name of Principal Investigator

Psychology

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February 27, 2020

Date

- End -