

A protocol for a randomized controlled clinical trial of on-demand acceptance and commitment training for burnout among medical students in Japan

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INTRO

- Burnout affects 30–50% of medical students globally ¹
- Japanese students face high burnout, low accomplishment ², and systemic barriers ³
- Existing interventions (e.g., mindfulness) lack scalability ⁴
- ACT enhances psychological flexibility and supports mental health ⁵⁻⁹
- Our prior face-to-face ACT pilot showed feasibility in Japan ¹⁰
- BEACON trial (Burnout to Engagement through ACT ON-demand):
 - First RCT of self-guided ACT for Japanese medical students

METHODS

- Design & Setting:** 2-arm online RCT (N=128) with Japanese 4th–6th year medical students in clinical clerkships (see Figure 1)
- Eligibility Criteria:** Moderate or greater burnout (OLBI-MS: EX ≥ 2.38 and/or DIS ≥ 2.25), internet access, ability to join online
- Recruitment & Allocation:** Nationwide online recruitment; stratified block randomization (1:1); allocation managed by independent staff
- Intervention:** 30-min online orientation → 3 self-guided ACT modules (Weeks 0–4) → online booster (Weeks 8–10) (see Table 1)
- Control Group:** No intervention; ACT access provided post-study

METHODS (cont'd)

- Outcomes:** Primary; medical students’ burnout (OLBI-MS), Secondary; helping professionals’ burnout (MBI-HSS), well-being (MHC-SF), psychological flexibility (WAAQ, VQ), depression (PHQ-9), stigma (MICA-4), ACT knowledge (ACT Check)
- Assessment Schedule:** 5 time points: Weeks 0, 2, 5, 8, and 14 (see Table 2)
- Sample Size Justification:** Based on medium effect size (d=0.5), α=0.05, power=0.80 → 64 per group
- Blinding:** Participants not blinded; outcome assessors blinded to group allocation
- Statistical Analysis:** Mixed-effects models for repeated measures (MMRM); intention-to-treat (ITT) approach; multiple imputation for missing data
- Data Management:** All data stored securely on university servers; monitored by research team under PI supervision

TRIAL STATUS

 Approved, pre-recruitment phase (as of June 2025)
Registered: [jRCT1042250024](https://www.clinicaltrials.gov/ct2/show/study?term=jRCT1042250024)

We developed and are testing an *on-demand* ACT intervention to reduce burnout and improve well-being in Japanese medical students during clerkships.
Self-paced. Values-driven. Culturally adapted.

Figure 1. CONSORT diagram: BEACON trial participant flow

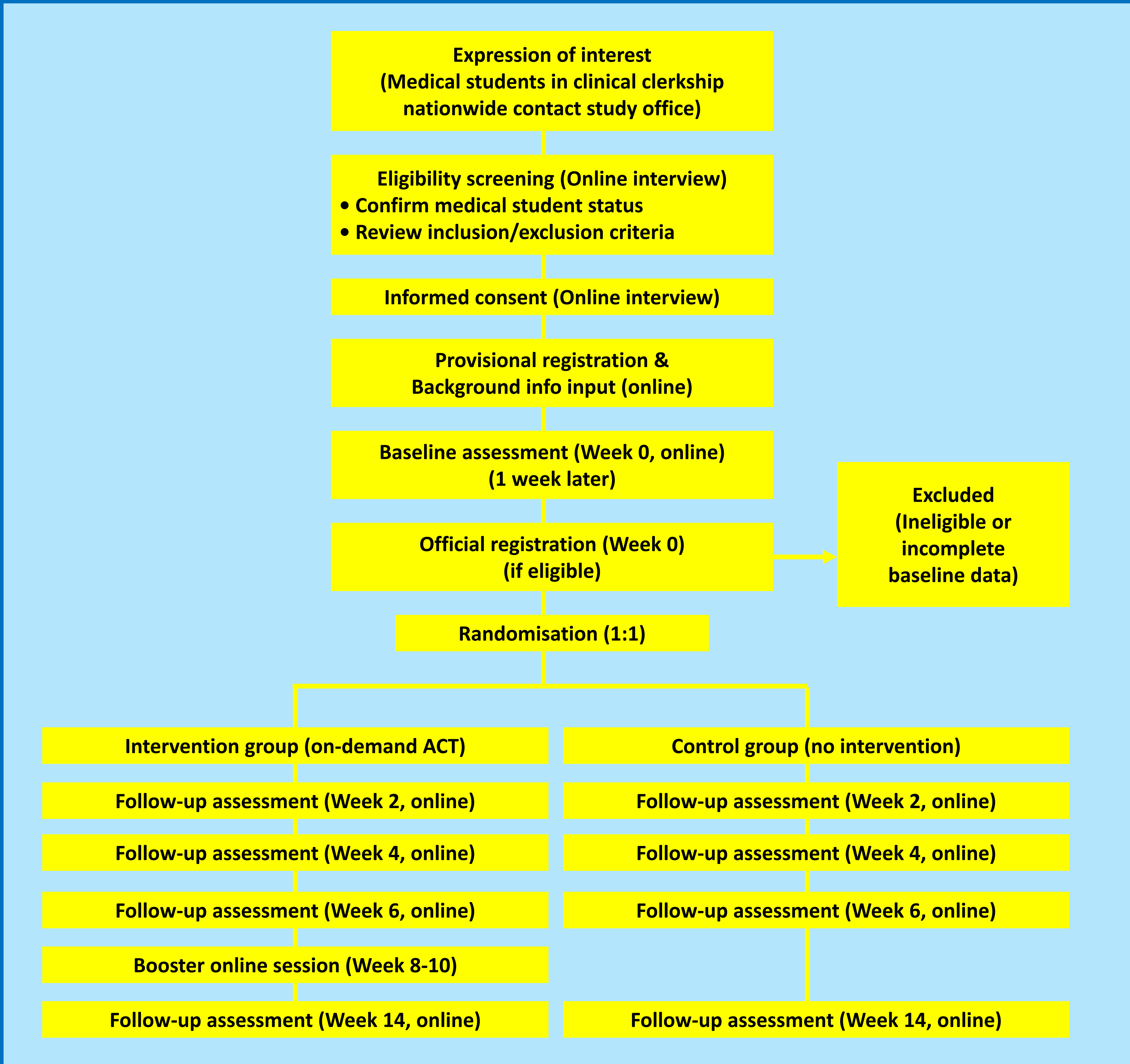


Table 2. Assessment Schedule and Measurement Time Points for Outcomes and Background Variables in the BEACON Trial

Measurement	Aim	Pre-baseline	Week 0 (Baseline)	Week 2	Week 4	Week 6	Week 14 (Follow-up)
Informed consent		X					
Eligibility assessment		X	X				
Background variables							
Demographic data		X					
AQ-J-21		X					
ASRS-J-6		X					
Primary outcome							
OLBI-MS	Burnout (medical students)		X	X	X	X	X
Secondary outcomes							
MBI-HSS	Burnout (helping professions)		X	X	X	X	X
MHC-SF	Well-being		X	X	X	X	X
PHQ-9	Depressive symptoms		X	X	X	X	X
VQ	Valued living (psychological flexibility)		X	X	X	X	X
WAAQ	Work-related psychological flexibility		X	X	X	X	X
MICA-4	Stigma toward mental illness		X	X	X	X	X
ACT Check	ACT knowledge	X					X

ACT Check, Acceptance and Commitment Therapy Check; AQ-J-21, Autism Spectrum Quotient–Japanese 21; ASRS-J-6, Adult ADHD Self-Report Scale Japanese 6; MBI-HSS, Maslach Burnout Inventory – Human Service Survey; MHC-SF, Mental Health Continuum–Short Form; MICA-4, Mental Illness: Clinicians’ Attitudes Scale version 4; OLBI-MS, Oldenburg Burnout Inventory for Medical Students; PHQ-9, Patient Health Questionnaire-9; VQ, Valuing Questionnaire; WAAQ, Work-related Acceptance and Action Questionnaire.

Table 1. Acceptance and Commitment Training (ACT) Program Overview

Time Point	Content Summary	Participant Activities
Week 0 After registration	Face-to-face online meeting (~20 min) <ul style="list-style-type: none">- Program orientation- Instructions for accessing on-demand videos- Brief lecture: Introduction to psychological flexibility<ul style="list-style-type: none">(1) How do you respond to negative thoughts or emotions?(2) Why do we try to control the uncontrollable?(3) What to do when control is ineffective?	- Attendance at online orientation
Week 0	On-demand video(1st session) (~90 min, viewable in segments) <ul style="list-style-type: none">- Introduction and practice of mindfulness and value-based behaviour- Mindfulness exercises (“raisin eating”, “noticing breath/body”)- Clarifying values (“80th birthday”, “important behaviour patterns”, “life compass”)- Action planning based on clarified values- Introduction to ACT Matrix- Preparation for next session- Comprehension test	- Watch video <ul style="list-style-type: none">- Complete comprehension test- Individual practice (1–2 weeks)
Week 2	On-demand video (2nd session) (~90 min, viewable in segments) <ul style="list-style-type: none">- Review of mindfulness/homework- “Hook” exercise (ACT Matrix)- Setting value-based goals and actions- Defusion exercises (“Humans vs Animals”, “Evolution of the Mind”, “Paper Pushing”, “Good Self, Bad Self”)- Acceptance exercise (“ice-holding”)- Preparation for next session- Comprehension test	- Watch video <ul style="list-style-type: none">- Complete comprehension test- Individual practice (1–2 weeks)
Week 4	On-demand video (3rd session) (~90 min, viewable in segments) <ul style="list-style-type: none">- Review of mindfulness/homework- Verbal Aikido (ACT Matrix)- Metaphor: “Demons on a Ship”- Self-message for the future- Compassion and equanimity- Preparation for next session- Comprehension test	- Watch video <ul style="list-style-type: none">- Complete comprehension test- Individual practice (2–4 weeks)
Week 8–10	Face-to-face online booster session (~30 min) <ul style="list-style-type: none">- Review of training/homework- Q&A session	- Attend booster session <ul style="list-style-type: none">- Individual practice (4–6 weeks)
Reminders & Monitoring	Throughout program <ul style="list-style-type: none">- Reminders (via email or phone) are sent if a participant has not viewed a session within 5 days.- Engagement points for participation	

DISCUSSION

STRENGTHS

- First RCT in Japan testing **on-demand ACT** for burnout and well-being in medical students
- Fully online **DCT design** enables broad access and flexibility
- Builds on a **validated face-to-face ACT pilot**
- Uses **multi-dimensional, validated measures** at multiple time points

LIMITATIONS

- Relies on **self-report** measures; lacks clinician-rated/objective outcomes
- No blinding** of participants or staff
- Short follow-up**; long-term effects remain unknown
- Possible **selection bias** from motivated participants

REFERENCE LIST

1. Almutairi H, Alsubaiei A, Abduljawad S, et al. *Int J Soc Psychiatry* 2022;68(6):1157-70.
2. Watanabe T, Akechi T. *BMC Psychiatry* 2023;23(1):302.
3. Komasa N, Terasaki F, Kawata R. *Med Teach* 2020;42(8):954-55.
4. Sperling EL, Hulett JM, Sherwin LB, et al. *PLoS One* 2023;18(10):e0286387.
5. Ditton E, Knott B, Hodyl N, et al. *JMIR Ment Health* 2023;10:e42566.
6. Flaxman PE, Bond FW. *J Occup Health Psychol* 2010;15(4):347-58.
7. Szarko AJ, Housmanfar RA, Smith GS, et al. *J Contextual Behav Sci* 2022;23:190-99.
8. Wang D, Lin B, Zhang S, et al. *J Med Internet Res* 2024;26:e50664.
9. Waters CS, Frude N, Flaxman PE, et al. *Br J Clin Psychol* 2018;57(1):82-98.
10. Watanabe T, Kondo M, Sakai M, et al. *J Contextual Behav Sci* 2023;30:20-30.

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