

Entitativity change for sustained reduction of stigma on mental illness

Submission date 11/09/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 07/10/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 08/10/2020	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Enhancing mental health literacy is a known effective intervention to reduce the stigma about mental illness. However, its sustainability in stigma reduction is questionable. Altering perceived entitativity (a sense of being a group) by manipulating antecedents like common goals and perceived similarities between people with and without mental health problems may have an additional value in sustaining the stigma reduction effect. The aim of this study is to assess the effect of entitativity change for the sustained reduction of stigma on mental illness.

Who can participate?

Students from University Malaysia Sarawak (UNIMAS)

What does the study involve?

Participants are required to complete a questionnaire before the intervention. They are randomly allocated to one of the two study groups. The allocation to a group is randomly generated by a computer. Participants receive an invitation via email to watch a video. At the end of the video presentation, they are asked to complete the questionnaire again. A month later, they are contacted to complete the questionnaire again.

What are the possible benefits and risks of participating?

There is no known risk as a result of participation in this study. However, participants are given a list of professional service providers if they are affected in any way. Alternatively, they may contact the researcher, whose contact details are provided in the information sheet. By participating in this study, participants will contribute to helping the researchers to improve the understanding of stigma about mental illness, and to reduce this stigma.

Where is the study run from?

University Malaysia Sarawak (UNIMAS) (Malaysia)

When is the study starting and how long is it expected to run for?

September 2020 to March 2020

Who is funding the study?
National University of Malaysia (Malaysia)

Who is the main contact?
Dr Marhani Midin
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Contact information

Type(s)
Scientific

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Public

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

NMRR-18-3033-39577

Study information

Scientific Title

Alteration of perceived entitativity for sustained reduction of stigma on mental illness: a randomized controlled trial

Study objectives

1. Interventional video A (altering perceived entitativity) is superior at sustaining reduction of stigma compared to interventional video B (personal narratives by client and knowledge shared by a psychiatrist)
2. Perceived entitativity can be delivered through vicarious (observational) learning

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 11/04/2019, the Research Ethics Committee of the National University of Malaysia (1st Floor, Clinical Block, Hospital Canselor Tunku Muhriz, UKM Medical Centr, Jalan Yaacob Latif, Bandar Tun Razak, 56000 Cheras, Kuala Lumpur, Malaysia; +603 (0)9145 5046/5048; intuiti_2011@yahoo.com), ref: UKM PPI/111/8/JEP-2019-259

Study design

Two-arm parallel group pragmatic randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Other

Participant information sheet

See additional files

Health condition(s) or problem(s) studied

Stigma about mental illness among university students

Interventions

Recruitment and sampling:

All students from University Malaysia Sarawak (UNIMAS) are invited to participate in this study. All students who can read, write and comprehend the English language are eligible for this study. The measurement tool used in this study is available and validated in English. Those who are unable to read and comprehend the English language are excluded. All students from UNIMAS met the basic English proficiency requirement with MUET (Malaysian University English Test) or equivalent tests. Students who consent to take part are given a survey form (online Google form) to fill up socio-demographic data. An information sheet with details of research objectives, description about the study, risk and benefit, confidentiality and a list of professional service providers is enclosed.

Randomization:

Participants are randomized into two interventional groups by using a computer-generated research randomiser (<https://www.randomizer.org>) by the primary investigator, who assigns participants to interventional groups.

Consenting participants are randomized into two interventional groups in which they: a) watch a video altering perceived entitativity by fixed goal-directed interactive activity; b) watch a video of personal narratives by the client and basic knowledge shared by a psychiatrist. Participants complete the baseline and post-intervention (immediately and at 1-month follow up) assessment by using the Reported and Intended Behaviour Scale (RIBS) questionnaire. The measurement tool used in this study (RIBS) is available and validated in English.

The intervention is given by a research investigator, and assessment is carried out by a research assistant blinded to the participant groups. Video A (altering perceived entitativity) and Video B (personal narratives by client and knowledge shared by a psychiatrist) are embedded in a Google form. All participants receive the Google form individually via email. Participants are asked to respond to a question to indicate if they have watched the video. It is made compulsory to watch the video before proceeding to respond to RIBS (immediately post-intervention) in the next section. The same RIBS are sent to all intervention attendees 1 month later for the follow-up response.

Video A was developed to alter perceived entitativity between two groups of people through a fixed goal-directed interactive activity. In this video, two pairs of individuals representing in-group (people without MHPs) and out-group (people with MHPs) were invited to complete an interdependence-based task. They shared feelings and past experiences throughout the task. It is postulated that this novel approach which aimed to diffuse the in-group and out-group differentiation would have greater and more sustainable effects in reducing stigma.

Video B is an intervention using the psychoeducation approach which represents the widely used intervention in the current state. This video serves as a control group. The psychoeducation approach has previously been proven to be effective in reducing stigma from an RCT. The trial team developed Video B with similar content from the DVD intervention by Clement. Video B comprises two parts of short clips including personal narratives by a client about his personal experience of mental health and stigma; and basic knowledge about symptoms and treatment approach of mental illness presented by a psychiatrist.

Intervention Type

Behavioural

Primary outcome measure

Intended behaviour to be in contact with people with a mental health problem (MHPs) in the future (intention to live with, work with, live nearby and continue a friendship with people having MHPs) measured using a Reported and Intended Behaviour Scale (RIBS) at baseline, immediately post-intervention, and at 1 month

Secondary outcome measures

Mean changes of RIBS score between 1-month follow-up and immediately post-intervention, measured using a Reported and Intended Behaviour Scale (RIBS) immediately post-intervention and at 1 month

Overall study start date

20/02/2019

Completion date

01/03/2020

Eligibility

Key inclusion criteria

Students from University Malaysia Sarawak (UNIMAS)

Participant type(s)

Other

Age group

Adult

Sex

Both

Target number of participants

178 participants would be needed to detect a standardised effect size of 0.143 on RIBS score with 99% power and a 0.05 (5%) significance level when comparing both interventional videos.

Key exclusion criteria

Unable to read and comprehend the English language as determined by the MUET (Malaysian University English Test) or equivalent tests

Date of first enrolment

20/09/2019

Date of final enrolment

01/12/2019

Locations

Countries of recruitment

Malaysia

Study participating centre

National University of Malaysia

Department of Psychiatry
Faculty of Medicine of National University of Malaysia
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Sponsor information

Organisation

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Sponsor type

University/education

Website

<http://www.ukm.my/v6/>

ROR

<https://ror.org/00bw8d226>

Funder(s)

Funder type

University/education

Funder Name

Universiti Kebangsaan Malaysia

Alternative Name(s)

Universiti Kebangsaan Malaysia (UKM), Universiti Kebangsaan Malaysia (UKM), Malaysia, ukminsta, Universiti Kebangsaan Malaysia - UKM, Universiti Kebangsaan Malaysia (Malaysia), University Kebangsaan (Malaysia), UKM

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

Malaysia

Results and Publications

Publication and dissemination plan

Planned publication in BMC Psychiatry following trial registration.

Intention to publish date

01/10/2020

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Lau Harn Ni (lauharnni@gmail.com). Type of data: patient's demographic data, response to questionnaire stored in Excel documents. The data will become available for 15 years. Access to the data is only by the research team and the REC UKM. The data was analysed by using SPSS. Written consent was obtained from all participants. The data is reported in a collective manner with no reference to an individual.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			08/10/2020	No	Yes