

# Entitativity change for sustained reduction of stigma on mental illness

<b>Submission date</b> 11/09/2020	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 07/10/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 08/10/2020	<b>Condition category</b> 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  
marhani@ppukm.ukm.edu.my

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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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  
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## **Sponsor information**

**Organisation**

National University of Malaysia

**Sponsor details**

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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?
<a href="#">Participant information sheet</a>			08/10/2020	No	Yes