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A theory-informed nurse-led web-based telenursing intervention for glycemic control in type 2 diabetes: a randomized controlled trial

Submission date 19/11/2022	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 01/12/2022	**Overall study status** Completed	
Last Edited 29/10/2026	**Condition category** Other	

Plain English summary of protocol

Background and study aims
Diabetes mellitus (DM) is a chronic metabolic disease that is the third largest cause of death in Indonesia, which is 6.7%. Indonesia is ranked 7th in the world and 3rd in Southeast Asia with 10.8 million sufferers. The prevalence of type 2 DM is increasing to 578 million in 2030 and 700 million in 2045. DM can cause complications that decreases quality of life, requires long-term care and high maintenance costs and give rise to psychological conditions in the form of mild stress. This impact must be controlled by managing the disease better using communication technology with telenursing to improve diabetes self-management behavior. This study aims to develop telenursing to improve the diabetes self-management of patients with type 2 DM.

Who can participate?
Patients aged 40-60 years old with type 2 DM who attend the endocrinology department in Panti Rapih hospital, Indonesia

What does the study involve?
Participants will be screened according to the inclusion criteria and randomly given an assignment to the control or intervention groups, they will not know which. The intervention group will be given education using telenursing and followed up using video calls every two weeks until 12 weeks. The control group will receive usual care with health education using leaflets, every month until three months. Participants in both the control and intervention groups will be measured at the baseline and week 12 for their level of knowledge, social and internal motivation, self-efficacy, and self-management of diabetes. In addition, participants will be measured for their level of knowledge and motivation in weeks 4 and 8, and self-efficacy and self-management in weeks 6.

What are the possible benefits and risks of participating?
The benefits for participants include learning about diabetes management from nurses and gaining motivation to change their health behavior, and also the ease of access to information by telenursing. A risk for participants is the use of their time while they partake in the intervention.

Where is the study run from?
Panti Rapih hospital (Indonesia)

When is the study starting and how long is it expected to run for?
September 2021 to May 2023

Who is funding the study?
Universitas Gadjah Mada (Indonesia)

Who is the main contact?
Theresia Titin Marlina, thtitin2020@mail.ugm.ac.id (Indonesia)

Contact information

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Additional identifiers

Study information

Scientific Title
Telenursing patients with type 2 diabetes mellitus for the improvement of glycemic control

Study objectives
Using telenursing can improve diabetes self-management compared to usual care

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/03/2022, Medical and Health Research Ethics Committee (MHREC) (Faculty of Medicine, Public Health and Nursing, Universitas Gadjah Mada-Dr Sardjito General Hospital, Indonesia; +62 811-2666-869; mhrec_fmugm@ugm.ac.id), Ref. KE/FK/0304/EC/2022

Primary study design
Interventional

Study design
Randomized controlled trial

Study type(s)
Other

Health condition(s) or problem(s) studied
Glycemic control

Interventions
Current interventions as of 29/10/2026:

The trial methodology is an interventional, single-blind, randomized, controlled trial. Researchers will screen patients according to the inclusion criteria. The researchers will then randomly assign 134 respondents to the study using a lottery. The 134 respondents will be randomized into groups using envelopes, including 67 patients in the intervention group and 67 in the control group. The participants will be blinded to which group they are in. The intervention group will receive health education through website-based telenursing and provide motivation and follow-up using video calls every two week until 12 weeks. The control group will receive usual care with health education using leaflets, every month until three months. The researcher will give information and motivation via telephone for approximately 15-20 minutes. The researcher will call the patients every two weeks. If they don't connect up to 3 times, they are declared disqualified. Participants in both the control and intervention groups will be measured at the baseline and week 12 for their level of knowledge, social and internal

motivation, self-efficacy, HbA1C, and self-management of diabetes. In addition, participants will be measured for their level of knowledge and motivation in weeks 4 and 8, and self-efficacy and self-management in weeks 6.

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Previous interventions:

The trial methodology is an interventional, single-blind, randomized, controlled trial. Researchers will screen patients according to the inclusion criteria. The researchers will then randomly assign 134 respondents to the study using a lottery. The 134 respondents will be randomized into groups using envelopes, including 67 patients in the intervention group and 67 in the control group. The participants will be blinded to which group they are in. The intervention group will receive health education through website-based telenursing and provide motivation and follow-up using video calls every two weeks until 12 weeks. The control group will receive usual care with health education using leaflets, every month until three months. The researcher will give information and motivation via telephone for approximately 15 minutes. The researcher will call the patients every two weeks. If they don't connect up to 3 times, they are declared disqualified. Participants in both the control and intervention groups will be measured at the baseline and week 12 for their level of knowledge, social and internal motivation, self-efficacy, and self-management of diabetes. In addition, participants will be measured for their level of knowledge and motivation in weeks 4 and 8, and self-efficacy and self-management in weeks 6.

Intervention Type
Behavioural

Primary outcome(s)
Current primary outcome(s) as of 29/10/2026:

HbA1C levels at baseline and weeks 12

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Previous primary outcome(s):

Diabetes self-management behaviors measured during video calls using the Summary Diabetes Self-Care Activities questionnaire (SDSCA) at baseline and weeks 6, and 12

Key secondary outcome(s)
Current key secondary outcome(s) as of 29/10/2026:

1. Level of knowledge measured using a Diabetes Knowledge Questionnaire at baseline and weeks 4, 8 and 12
2. Fatalism measured using a Diabetes Fatalism Scale and Social support with MOS_Social Support Survey at baseline and weeks 4, 8 and 12
3. Self-efficacy measured using a Diabetes Mellitus Self Efficacy Scale at baseline and weeks 6 and 12
4. Diabetes Self Management measured using SDSCA

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Previous key secondary outcome(s):

1. Level of knowledge measured during video calls using a Diabetes Knowledge Questionnaire at baseline and weeks 4, 8 and 12
2. Motivation measured using a Diabetes Fatalism Scale and MOS_Social Support Survey at baseline and weeks 4, 8 and 12
3. Self-efficacy measured using a Diabetes Mellitus Self Efficacy Scale at baseline and weeks 6 and 12

Completion date
05/05/2023

Eligibility

Key inclusion criteria
1. Patients diagnosed with type 2 diabetes mellitus examined at the endocrine clinic
2. Aged 40-60 years old
3. Patients have HbA1C levels of at least 6.5% in the last three months
4. The patient has an Android phone and has installed a website browser and WhatsApp
5. Able to open a website browser and use WhatsApp
6. Willing to be a respondent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
134

Key exclusion criteria
1. Anemia (Hb ≤ 11 gr/dl) based on the doctor's diagnosis and has no history of blood transfusions in the last 2-3 months because it affects HbA1C levels
2. Impaired kidney function based on the doctor's diagnosis because it will affect hemoglobin levels and affect dietary information in the management of diabetes
3. Experiencing heart problems
4. Depression, dementia, and cognitive impairment based on the doctor's diagnosis because it can affect the patient's self-management ability

Date of first enrolment
03/12/2022

Date of final enrolment

01/02/2023

Locations

Countries of recruitment
Indonesia

Study participating centre
Panti Rapih Hospital
Cik Di Tiro Street 30
Yogyakarta
Indonesia
55223

Sponsor information

Organisation
Gadjah Mada University

ROR
https://ror.org/03ke6d638

Funder(s)

Funder type
University/education

Funder Name
Universitas Gadjah Mada

Alternative Name(s)
Gadjah Mada University, UGM

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Indonesia

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analyzed during the current study will be published as a supplement to the results publication.

IPD sharing plan summary

Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			28/11/2022	No	Yes