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Effectiveness of text message reminder and motivational interview on adherence to methadone treatment in Vietnam

Submission date
07/10/2024

Recruitment status
No longer recruiting

Registration date
15/10/2024

Overall study status
Completed

Last Edited
15/10/2024

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Methadone maintenance treatment (MMT) for opioid dependence has been widely used in many countries and has demonstrated effectiveness. Despite its effectiveness, non-adherence or poor adherence rates can reach up to 70%. Hence, various initiatives have been implemented and reported to improve adherence, including motivational interviews (MI) and text message reminders (TMR). Motivational enhancement through TMR and MI plays a pivotal role in addressing substance use and facilitating enduring recovery. However, to date, there has been no study on the impact of these methods in enhancing treatment adherence among methadone patients in Vietnam, especially in Ho Chi Minh City (HCMC). This study aims to assess the effectiveness of MI and TMR on treatment adherence among MMT patients in HCMC after three and six months of intervention. The findings will serve as a critical basis for proposing and developing practical interventions and support for these patients.

Who can participate?
Patients aged 18 years old and above who are able to attend three MMT clinics during the study period

What does the study involve?
The study consisted of three groups: control, TMR, and MI. Participants at each location were randomly allocated into three groups at district 6, district 8 and Binh Thanh district clinics. Within each clinic, patients were then randomly assigned to one of these three predefined groups. For the control group, patients were treated according to the standard guidelines of the Vietnamese Ministry of Health. For the MI group, patients underwent counseling sessions at least twice a month, typically lasting 10-20 minutes per patient, with flexibility for longer sessions based on individual needs and concerns. Each patient maintained a progress monitoring record throughout the 6-month intervention period, which included specific directives to explore the patient's information and factors influencing their health, based on the four stages of MI: engaging, focusing, evoking, and planning. Patient progress was monitored through observed behavioral changes and the application of key MI techniques, while also assessing readiness, importance, self-efficacy, and commitment across all intervention phases. This

approach ensured continuous monitoring of patient advancement and timely provision of personalized support. For the TMR group, messages were sent using the brand name "FamilyMMT", following a structured schedule: three messages in the first week (at the beginning, middle, and end), two in the second week (at the beginning and end), and one in the third week (at the end), repeated in a cycle of weeks 1, 2, and 3. Patients in the intervention groups (MI and TMR) were monitored monthly over the 6-month period, with their achievement records announced and displayed in the designated counseling room for the study. Patient progress was assessed based on daily dosage adherence and monthly urine test results, extracted from the S.STORM dose management software in the dispensing department and standard testing result management software in the laboratory. Treatment adherence data was extracted from the dispensing department database and the daily dose management software, and categorized.

What are the possible benefits and risks of participating?
During the process of participating in the research, participants will receive free advice from experts who are lecturers at Ho Chi Minh City University of Medicine and Pharmacy, HCMC, if and when they need advice related to mental health or psychology. For the time spent on the questionnaire survey, they will receive 3 days of medication support for each time participation in the questionnaire interview. This participation and the information gained will help to plan the services to help them and other patients on methadone treatment.

There should not be any further inconveniences, risks, discomforts or side effects, effects to any questions.

Where is the study run from?
This study was carried out at three clinics located in District 6, District 8, and Binh Thanh District, which were among the first clinics to implement the MMT program in Vietnam

When is the study starting and how long is it expected to run for?
Febraury 2018 to January 2019.

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr. Le Nu Thanh Uyen, lenuthanhuyen@ump.edu.vn

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Effectiveness of text message reminder and motivational interview on adherence to methadone treatment in Vietnam: a randomized controlled trial

Acronym
TMR MI MMT

Study objectives
Text message reminders and motivational interviewing increase adherence to methadone treatment

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 15/03/2018, The Ethics Committee for Biomedical Research at the University of Medicine and Pharmacy in Ho Chi Minh City (217 Hong Bang Street, Ward 11, District 5, Ho Chi Minh City, 700000, Viet Nam; +84 28 38556284; nghiencuukhoahoc@ump.edu.vn), ref: 95/DHYD-HDDD

Study design
Multicenter interventional non-blinded randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community, Home, Medical and other records

Study type(s)
Efficacy

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Treatment adherence on methadone maintenance treatment patients

Interventions
For the control group, patients were treated according to the standard guidelines of the Vietnamese Ministry of Health. They received the same services previously provided by the clinics, including daily methadone intake, counseling, follow-up appointments, and urine testing as per the MMT program's regulations.

For the motivational interview (MI) group, patients underwent counseling sessions at least twice a month, typically lasting 10-20 minutes per patient, with flexibility for longer sessions based on individual needs and concerns. Each patient maintained a progress monitoring record throughout the 6-month intervention period, which included specific directives to explore the patient’s information and factors influencing their health, based on the four stages of MI: engaging, focusing, evoking, and planning. Patient progress was monitored through observed behavioral changes and the application of key MI techniques, while also assessing readiness, importance, self-efficacy, and commitment across all intervention phases. This approach ensured continuous monitoring of patient advancement and timely provision of personalized support.

For the text message reminder (TMR) group, messages were sent using the brand name “FamilyMMT”, following a structured schedule: three messages in the first week (at the beginning, middle, and end), two in the second week (at the beginning and end), and one in the third week (at the end), repeated in a cycle of weeks 1, 2, and 3. Typically dispatched early in the morning, around 6-8 am, or in the evening before 9 pm, these messages were composed of predetermined templates or adjusted as needed in response to sudden contextual changes, such as weather variations (rain, wind, storms, intense sunshine, festivals), which might impact patients’ daily attendance for medication intake. The messages served as both reminders and motivational encouragements for patients, with the content incorporating four categories aligned with the MI approach: greetings, announcements, congratulations, and thanks (Category 1); motivational reminders (Category 2); encouragement of positive behaviors (Category 3); and provision of emotional support, empathy, and care (Category 4).

Patients in the intervention groups (MI and TMR) were monitored monthly over the 6 months, with their achievement records announced and displayed in the designated counseling room for the study. Patient progress was assessed based on daily dosage adherence and monthly urine test results, extracted from the S.STORM dose management software in the dispensing department and standard testing result management software in the laboratory.

To ensure the representativeness of patient characteristics, a systematic random sampling method based on the patient list at each clinic was utilized to select participants, with a sampling interval of 2, meaning that for every two patients from the existing list at each clinic, one was selected and invited to participate in the study. To minimize differences in patient

characteristics, healthcare workers, and services at each clinic, the sample size was divided using a stratified random sampling method. Participants at each location were randomly allocated into two groups: District 6 (75 MI and 75 TMR), District 8 (75 MI and 75 control), and Binh Thanh District (75 TMR and 75 control). Within each clinic, patients were then randomly assigned to one of these two predefined groups.

Intervention Type
Behavioural

Primary outcome measure
Treatment adherence data was measured using data extracted from the dispensing department database and the daily dose management software, and categorized into three groups: complete adherence, consecutive adherence, and weekend adherence at baseline, after 3 months of intervention, after 6 months of intervention

Secondary outcome measures
The following secondary outcome measures, unless stated, were measured using data extracted from the dispensing department database and the daily dose management software, and categorized into three groups: complete adherence, consecutive adherence, and weekend adherence:
1. Complete adherence, defined as patients adhering fully (100%) without missing any doses over the past three months
2. Consecutive adherence, defined as patients not missing three or more consecutive doses within the past three months
3. Weekend adherence, defined as patients not missing any doses over the past weekend
4. Tobacco addiction measured using the Fagerström Test for Nicotine Dependence (FTND) at baseline, after 3 months of intervention, and after 6 months of intervention
5. Alcohol use measured using the Alcohol Use Disorders Identification Test (AUDIT) at baseline, after 3 months of intervention, and after 6 months of intervention
6. The availability of social support measured using the Medical Outcomes Study – Social Support Survey (MOS-SSS) at baseline, after 3 months of intervention, and after 6 months of intervention
7. Interpersonal trust in patient-physician relationships measured using the Trust in Physician Scale (TPS), where higher scores reflect greater trust Satisfaction and the treatment facility assessed using a 5-point Likert scale at baseline, after 3 months of intervention, and after 6 months of intervention
8. General health status measured using the EuroQol - 5 Dimensions - 5 Levels (EQ-5D-5L) and the EuroQol - Visual Analogue Scale (EQ-VAS) at baseline, after 3 months of intervention, and after 6 months of intervention
9. Comorbidities and ARV treatment measured using data obtained from medical records at one timepoint

Overall study start date
15/02/2018

Completion date
31/01/2019

Eligibility

Key inclusion criteria

1. Aged 18 years old and over
2. Willing to participate
3. Able to attend the methodone maintenance treatment (MMT) clinics during the study period were recruited from the three MMT clinics.

Participant type(s)
Patient

Age group
Adult

Lower age limit
19 Years

Upper age limit
63 Years

Sex
Both

Target number of participants
150 patients per group; total of 450 patients

Total final enrolment
450

Key exclusion criteria
1. Unable to communicate because of any health problem that is considered limited, too weak to participate such as a serious illness
2. Serious neurological problems
3. Has been arrested during methodone maintenance treatment (MMT) have violated the law such as gathering to use drugs, illegally trading drugs or disrupting social order and security such as: robbery, murder. There were no links during the initial survey period of more than one week.

Date of first enrolment
26/04/2018

Date of final enrolment
25/05/2018

Locations

Countries of recruitment
Viet Nam

Study participating centre
Community consultation and support department - District 6 Methadone Clinic
1039A Hong Bang street, ward 12, district 6
Ho Chi Minh city

Viet Nam
700000

Study participating centre
Community consultation and support department - District 8 Methadone Clinic
1724 Pham The Hien street, district 8
Ho Chi Minh City
Viet Nam
700000

Study participating centre
Community consultation and support department – Binh Thanh District Methadone Clinic
104 Dinh Bo Linh street, ward 26, Binh Thanh district
Ho Chi Minh City
Viet Nam
700000

Sponsor information

Organisation
Ho Chi Minh City Medicine and Pharmacy University

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Sponsor type
University/education

ROR
https://ror.org/025kb2624

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
04/10/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr Le Nu Thanh Uyen, lenuthanhuyen@ump.edu.vn.

The research results will be shared with research participants, methadone clinics where patients are being treated directly and shared with Methadone clinics in Vietnam, and the publication of domestic and foreign articles. All shares will be anonymous. The doctoral thesis will be stored at three national academic libraries in Vietnam: The Library at the University of Medicine and Pharmacy, Ho Chi Minh City, the National Library in Ho Chi Minh City and the National Library in Hanoi, Vietnam. Once the data are collected and approved, the doctoral thesis defense committee will announce the results to patients, and methadone clinics and publish articles.

In the patient information sheet and consent form to participate in the research, there is information for the patient about who the data will be shared and the patient knows that articles will be published domestically and internationally for this research (attached files: information statement for participants, consent form). All aspects of the study, including data and results, will be treated confidentially and only the researcher will have access to participant information. The patient number is required to collect information about their treatment, but no identifying information will be needed in the questionnaire. Only the researchers named above know which set of questions belongs to whom. Only our codes are used to identify question sets. Data will be stored in a locked cabinet at the office of the Department of Community Health, University of Medicine and Pharmacy at Ho Chi Minh City for 3 years and then all questionnaires will be shredded and destroyed by the researcher. A report of this research may be submitted for publication, but the individuals participating will not be identified in the report. This study received ethical approval from the Ethics Committee for Biomedical Research at the University of Medicine and Pharmacy in Ho Chi Minh City and all MMT clinics involved in the study.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			14/10/2024	No	Yes
Participant information sheet			14/10/2024	No	Yes