

Drug counselling to improve the taking of short-term antibiotics as prescribed

Submission date 12/12/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 22/12/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 29/09/2022	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Medication adherence usually refers to whether patients take their medications as prescribed (eg, twice daily), as well as whether they continue to take a prescribed medication. An earlier study showed that drug adherence information provided in pharmacies by pharmacy staff takes about 2 to 3 minutes and is usually delivered in a hurry and unstructured. Drug counselling between providers and patients takes longer and is very rare, and has never been done in some pharmacies. The researchers have developed a modified counselling model to help improve pharmaceutical counselling services. The aim of this study is to test the effect of this model.

Who can participate?

Adult patients who come to the pharmacy to buy antibiotics.

What does the study involve?

Patients at the pharmacy who are willing to take part in the study are randomly allocated to receive either advice as usual, or a 15-minute drug counselling session with pharmacy staff to explain the name of the drug, what it is for, dosage, frequency of use, duration of use, possible symptoms, and how to store the medicine in detail.

What are the possible benefits and risks of participating?

There are no expected benefits or risks for participants.

Where is the study run from?

Community pharmacies in Bali (Indonesia)

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

September 2020 to April 2021

Who is funding the study?

Investigator initiated and funded

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
KFI/2020

Study information

Scientific Title
Modification of pharmaceutical counseling enhances patient adherence with short-term antibiotics use compared with conventional drug information

Acronym
MPH

Study objectives
The modified counseling enhances adherence with short-term antibiotic use in pharmacy patients.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 26/10/2020, Research Ethics Committee, Faculty of Medicine, Udayana University (Pulau Serangan Street, Denpasar, Bali, 80114, Indonesia; +62 (0)361 227911-15; no email provided) ref: 2144/UNUN.14.2.2.VII.14/LT/2020

Study design

Interventional randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied

Patient adherence to short-term antibiotics

Interventions

A baseline survey is conducted to measure the level of knowledge and attitudes of short-term antibiotic use in pharmacy patients.

Participants are randomly allocated to the intervention group and the comparison group. The randomization process is carried out by block-randomization with 1 day intervals, for example Monday is the intervention group, Tuesday is the comparison group and so on.

The intervention of modified counselling consists of explaining to the patient the name of the drug, indication, dosage, frequency of use, duration of use, possible symptoms, and how to store the medicine in detail. The intervention is conducted by a trained pharmacist assistant in a private room. The duration of follow-up is based on when the drug is consumed by the patient, ranging from 3-7 days depending on the amount of drug given in the doctor's prescription.

In the comparison group, the patient is given conventional drug information by the pharmacist's assistant on duty.

For baseline data, the researchers conduct a self-administered questionnaire with pharmacist patients, then for adherence measurements they use a telephone call to interview the participants.

Intervention Type

Behavioural

Primary outcome measure

Patients adherence measured using Morisky Medication Adherence Scale -8 by telephone questionnaire when the drug is predicted to run out, 3-7 days from the time the patient came to the pharmacy to buy the drug

Secondary outcome measures

Problems arising in patient adherence or non-adherence to antibiotic therapy and the opinions of various parties on the implementation of the modified pharmaceutical counseling, collected by telephone interviews with patients (3-7 days from the time the patient came to the pharmacy to buy the drug) and interviews with service providers (at the pharmacy during the participant recruitment) and policyholders (at any convenient time and place during the data collection by appointment)

Overall study start date

21/09/2020

Completion date

30/04/2021

Eligibility

Key inclusion criteria

1. Aged ≥ 18 years
2. Come to the pharmacy to buy antibiotics by prescription
3. Willing to become respondents by agreeing to the informed consent

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

300

Total final enrolment

300

Key exclusion criteria

Patients who are doctors, nurses, midwives and other health workers

Date of first enrolment

01/12/2020

Date of final enrolment

15/03/2021

Locations

Countries of recruitment

Indonesia

Study participating centre

Apotek Kimia Farma 34

Diponegoro Street 125

Denpasar Bali

Indonesia

80114

Study participating centre

Apotek Kimia Farma 108

Teuku Umar Street

Denpasar Bali

Indonesia

80113

Study participating centre

Quantum Clinic

Sesetan Street

Denpasar Bali

Indonesia

80114

Study participating centre

Sad Dasa Clinic

Candidasa Streets

Karangasem Bali

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Sponsor information

Organisation

Udayana University

Sponsor details

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Sponsor type

University/education

Website

<http://www.unud.ac.id/eng/>

ROR

<https://ror.org/035qsg823>

Funder(s)**Funder type**

Other

Funder Name

Investigator initiated and funded

Results and Publications**Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

01/09/2022

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/09/2022	29/09/2022	Yes	No