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

Submission date	Recruitment status	[_] Prospectively registered
12/12/2020	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
22/12/2020	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
29/09/2022	Other	

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

Protocol serial number
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

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s))
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)

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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 Strees
Karangasem Bali
Indonesia
80811

Sponsor information

Organisation
Udayana University

ROR
https://ror.org/035qsg823

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

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