

Effect of interventions to improve the use of inhalers as instructed by the health care provider

Submission date 21/10/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 01/11/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 11/11/2022	Condition category Respiratory	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Taking medications (or other treatment) exactly as instructed by a health care provider (adherence) is the key to the success of any treatment. It is well established that adherence in chronic diseases is low, in the range of 30-70%. The adherence rate is much lower for inhalers compared to other dosage forms. Non-adherence leads to inadequate disease control and increased healthcare cost. Jawaharlal Institute of Postgraduate Medical Education and Research (JIPMER) is a Government of India-funded health care centre. JIPMER is the only institution that provides dry powder inhalers (Rotahaler) and rotacaps free of cost to treat patients with CRDs. Hence, it attracts patients not only from Puducherry, but also from the neighbouring districts of Tamil Nadu. These drugs are prescribed to about 1,000 patients every month. Both the Rotahaler and the beclomethasone dipropionate rotacaps are among the high-priced drugs procured in JIPMER. However, there is no policy to check the correct use of these drugs and the proper inhaler technique among these patients. This work studies the adherence to inhalers among patients with CRDs, the correct use of the inhaler, and enhance adherence through counselling and reminders through mobile phones.

The aim is to assess the effectiveness of sending reminders through mobile phones and patient counselling to improve adherence among patients with chronic respiratory disease using inhalers in a tertiary care centre in Puducherry.

Who can participate?

Adult patients with the diagnosis of asthma or COPD being followed in JIPMER Medicine or Pulmonary Medicine Outpatient Department and using the inhaler for at least three months at the time of recruitment to the study. Both male and female patients aged from 14 to 80 years with or without other co-morbid conditions were included in the study. Patients should own a mobile phone.

What does the study involve?

Patient counselling and recorded voice call reminders were the two interventions tested to improve adherence. Patients were randomized into four groups. Group 1 received both

interventions, group 2 received patient counselling alone, group 3 received voice call reminders alone and group 4 received usual treatment. All groups received baseline treatment, i.e., teaching on inhaler technique.

What are the possible benefits and risks of participating?

Patients gain knowledge about the disease and drug. Improved adherence leads to better disease control and improved quality of life. Since no new treatments or drugs were involved in the trial, no new side effects were expected. No risks were involved in participating in the study.

Where is the study run from?

JIPMER (India)

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

May 2015 to December 2019

Who is funding the study?

JIPMER Intramural Fund (India)

Who is the main contact?

Manjulakshmi Padmanabhan, manjulakshmi.p@gmail.com

Contact information

Type(s)

Public

Contact name

Ms Manjulakshmi P Padmanabhan

ORCID ID

<https://orcid.org/0000-0002-9831-0669>

Contact details

E-41 JIPMER campus

Danvantri Nagar

Gorimedu

Puducherry

India

605006

+90 (0)7598376368

manjulakshmi.p@gmail.com

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

JIP/IEC/2015/15/571

Study information

Scientific Title

The effect of interventions to improve adherence to inhaled medications in patients with chronic respiratory diseases

Study objectives

Sending reminders to mobile phones and patient counselling to improve adherence among patients with chronic respiratory disease using inhalers in a tertiary care centre in Puducherry were effective

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 28/05/2015, Institute Ethics Committee Human Studies, Jawaharlal Institute of Postgraduate Medical Education and Research (JIPMER, JIPMER Campus Road, Gorimedu, Dhanvantari Nagar, Puducherry 605006, India; +091-0413-2298288; research@jipmer.edu.in), ref: ECR/342/Inst/PY/2013

Study design

Single-center interventional 2x2 factorial randomized controlled trial

Primary study design

Interventional

Study type(s)

Other

Health condition(s) or problem(s) studied

Asthma and chronic obstructive pulmonary disease (COPD)

Interventions

Patients were randomized into four groups. Group 1 received both interventions, group 2 received patient counselling alone, group 3 received voice call reminders alone and group 4 received usual treatment. All groups received baseline treatment, i.e., teaching on inhaler technique.

Control: Patients were shown a video explaining the technique of inhaler use. This video was downloaded from YouTube (<https://www.youtube.com/watch?v=fVPKNl2tNu4>) with the title "Learn how to use a Rotahaler Inhale" on demonstration of Rotahaler that M/s Cipla uploaded. This video explains the steps in the use of Rotahaler. After watching the video, patients were asked to demonstrate the technique. Any steps that were missed or done incorrectly were rectified on the spot.

Patient counselling: This involves face-to-face counselling with the recruited patients in groups 1 and 2. This counselling focuses on clarifying patients' beliefs about disease, which were

identified as barriers to adherence. The topics to be discussed during patient counselling were identified by semi-structured interviews conducted before the start of the study. In brief, the topics discussed were:

- (1) The disease process in chronic respiratory diseases (CRD) and its chronic nature
- (2) The role of allergy in asthma and their belief about food-induced allergy. The role of smoking in COPD patients
- (3) The need to take drugs regularly
- (4) The need to follow a healthy lifestyle with balanced nutrition and exercise
- (5) Any other doubts the patients may raise were also clarified

Voice call reminders: Patients in groups 1 and 3 received recorded voice calls. A recorded voice call message was sent twice a week to their mobile phones in their vernacular language, encouraging them to take their medications regularly. The message was for 20 seconds. Voice call messages would advise patients to take their steroids (red rotacaps) regularly and a note to contact their healthcare provider in case of uncontrolled disease.

Randomization:

A randomization table was created using the Random Allocation Software. A computer-generated randomized sequence was made by a person not involved in the study. These were placed in sequentially numbered opaque sealed envelopes and handed over to the investigator. This was used for randomizing the patients to one of the four treatment groups.

Intervention Type

Behavioural

Primary outcome(s)

Self-reported adherence measured using 8-item Morisky Medication Adherence Questionnaire at baseline, third month and sixth month.

Key secondary outcome(s)

1. Prescription refill data measured using the proportion of days covered at six months before intervention and six months during the intervention
2. Severity of disease measured using lung capacity (FEV1(%)) at baseline, third month and sixth month

Completion date

20/12/2019

Eligibility

Key inclusion criteria

1. Patients diagnosed with asthma or COPD and followed up in JIPMER Medicine or Pulmonary Medicine outpatient department, three months prior to the study period with or without other co-morbid conditions
2. The patients should own a mobile phone and be able to use it

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

421

Key exclusion criteria

1. Patients who should refrain from performing PFT, as in the case of patients with pneumothorax, history of recent MI or pulmonary embolism, abdominal or cerebral aneurysm
2. Patients who had undergone recent surgery
3. Patients who were hard of hearing or mentally disabled

Date of first enrolment

20/03/2017

Date of final enrolment

10/06/2019

Locations**Countries of recruitment**

India

Study participating centre

Jawaharlal Institute of Postgraduate Medical Education and Research

JIPMER Campus Road

Gorimedu

Dhanvantari Nagar

Gorimedu

Puducherry

India

605006

Sponsor information**Organisation**

Jawaharlal Institute of Post Graduate Medical Education and Research

ROR

<https://ror.org/02fq2px14>

Funder(s)

Funder type

University/education

Funder Name

Jawaharlal Institute Of Postgraduate Medical Education and Research

Alternative Name(s)

JIPMER

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

India

Results and Publications

Individual participant data (IPD) sharing plan

The principal investigator is willing to share the de-identified participant level data.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files	Case report form		27/10/2021	No	No
Protocol file			27/10/2021	No	No