

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

<b>Submission date</b> 21/10/2021	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 01/11/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 11/11/2022	<b>Condition category</b> 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**

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## Additional identifiers

**EudraCT/CTIS number**

Nil known

**IRAS number**

**ClinicalTrials.gov number**

Nil known

## **Secondary identifying numbers**

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

## **Secondary study design**

Randomised controlled trial

## **Study setting(s)**

Hospital

## **Study type(s)**

Other

## **Participant information sheet**

No participant information sheet available

## **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 measure**

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

## **Secondary outcome measures**

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

## **Overall study start date**

28/05/2015

**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

**Age group**

Adult

**Sex**

Both

**Target number of participants**

440

**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

### Sponsor details

JIPMER Campus Road  
Dhanvantari Nagar  
Gorimedu  
Puducherry  
India  
605006  
+91-0413-2298288  
research@jipmer.edu.in

### Sponsor type

University/education

### Website

<http://jipmer.edu.in/>

### 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

## Publication and dissemination plan

Planned publication in a peer-reviewed journal

## Intention to publish date

01/05/2023

## 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?
<a href="#">Other files</a>	Case report form		27/10/2021	No	No
<a href="#">Protocol file</a>			27/10/2021	No	No