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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

Registration date
01/11/2021

Overall study status
Completed

Last Edited
11/11/2022

Condition category
Respiratory

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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

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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
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Sponsor information

Organisation
Jawaharlal Institute of Post Graduate Medical Education and Research

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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 the 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