ISRCTN33776525 https://doi.org/10.1186/ISRCTN33776525

Impact of a community pharmacy based information program on type 2 diabetic patients' adherence to their oral treatment

Submission date
03/03/2017

Recruitment status
No longer recruiting

Registration date
25/04/2017

Overall study status
Completed

Last Edited
01/05/2020

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Diabetes is a lifelong (chronic) condition that causes a person's blood sugar level to become too high. A survey found that although 80% of patients with type 2 diabetes say they are well informed, 71% would like other additional information. Only 17% of the same patients report receiving instruction in addition to their treatment. Pharmacists could exert a major effect on treatment adherence in chronic disease. The aim of this study to assess the impact of information provided by community pharmacists on patients' adherence to treatment.

Who can participate?
Patients aged over 18 with type 2 diabetes

What does the study involve?
Participants are randomly allocated to one of two groups. Participants in one group attend interviews with a pharmacist three times over 6 months (once every 2 months) covering diet, drug treatment and the complications of diabetes. Each interview lasts about thirty minutes and involves general monitoring of the patient and then giving the patient a brochure which is an opening for a discussion between the pharmacist and the patient. Participants in the other group receive treatment as usual. The impact on treatment adherence is assessed in both groups after 6 months by the pharmacist counting the tablets remaining in the treatment packs delivered to the patient during the previous visit.

What are the possible benefits and risks of participating?
The benefits for the patient are a better knowledge of diet and the complications of diabetes, as well as better management of their treatment. There are no expected risks for the participants.

Where is the study run from?
182 pharmacies in France

When is the study starting and how long is it expected to run for?
March 2014 to December 2016

Who is funding the study?
Merck (USA)

Who is the main contact?
Dr Yves Michiels

Contact information

Type(s)
Scientific

Contact name
Dr Yves Michiels

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
012014

Study information

Scientific Title
Impact of a community pharmacy based information program on type 2 diabetic patients' adherence to their oral treatment (IPhODia): a randomized cluster study vs usual practice

Acronym
IPhODia

Study objectives
Diabetes is a prime example of a chronic disease which is increasingly prevalent in France (38% in 7 years) and accounts for nearly 10% of our health spending. The many complications associated with diabetes contribute substantially to this spending and occur when diabetes is insufficiently controlled. The current therapeutic objective of the treatment is measured by the level of Hba1C which should be < 7% as defined by NHANES.

In France, despite significant improvements in the follow up of type 2 diabetes patients, the last results of Entred 2007-2010 are showing an insufficient level of control with too many patients with HbA1C>7%. This epidemiological study points to improved control of cardiovascular risk

factors (lipid profile, high blood pressure) but still inadequate control of glycaemia. Some 41% of people with type 2 diabetes have HbA1c levels above 7% and 15% have levels above 8%.

These figures, testifying to failed therapy, are the source of many hospitalizations especially as glycaemic balance is not achieved. Alongside this, the costs of cover are proportional to this absence of control. The annual cost of a diabetic patient rises from $2 792 for an HbA1c < 7% to $6 759 for an HbA1c of 10%. Several additional measures should be contemplated to make therapy more efficacious. Adherence or rather non-adherence is inherent in chronic drug treatment and for diabetes, many studies are increasingly highlighting adherence as a factor for successful or unsuccessful drug treatment. Adherence seems to be one of the key points for the successful treatment of a chronic diseases like diabetes.

General practitioners remain the prime point-of-contact for diabetic patients, in spite of regular controls, physicians encounter difficulties correctly informing their patients mainly due to a lack of time and means. Diabetic patients must, in the majority (90%) of cases, go to the pharmacy for their treatment to be renewed and dispensed. This should be a useful opportunity for detecting and correcting any decline in adherence. Pharmacists, who are par excellence specialists in medication, are an essential actor and thanks to their expertise, their large number and their accessibility, pharmacists could play a beneficial role in patient adherence.

The IPhODia study aims to assess the impact on adherence of specific information provided by community pharmacists.

Ethics approval required
Old ethics approval format

Ethics approval(s)
In France a clinical trial such as IPhODia does not require ethics approval

Study design
Prospective multicentre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Diabetes

Interventions
The intervention consists of three different pharmaceutical interviews during 6 months (one every 2 months) covering thematic information on diabetes, namely diet for diabetics, monitoring drug treatment and the complications of diabetes. Each interview is composed of two parts and lasts about 30 minutes. It involves first general monitoring of the diabetic patient and then giving the patient a thematic information brochure which is an opening for a discussion between the pharmacist and the patient.

In order to demonstrate the effectiveness of this intervention, a randomised study is performed with two groups of patients, one receiving information from the pharmacists according to the program, the other receiving treatment as usual. Impact on adherence will be assessed using the Medication Possession Ratio (MPR) at 6 months.

Intervention Type
Other

Primary outcome measure
Medication Possession Ratio (MPR), measured by the pharmacist by counting tablets remaining in the treatment packs delivered to the patient during the previous visit, at 6 months

Secondary outcome measures
1. HbA1c level, measured by laboratory analysis at 6 months
2. Adherence, measured by a specific questionnaire (TOP) at 6 months
3. Patient’s knowledge acquisition, measured by a specific questionnaire developed by the scientific committee at 6 months
4. Patient’s satisfaction, measured by a specific questionnaire developed by the scientific committee, for the patients in group A at 6 months

Overall study start date
01/03/2014

Completion date
31/12/2016

Eligibility

Key inclusion criteria
1. Men or women
2. Age >18 years
3. Diabetics with less four oral antidiabetics medications
4. HbA1c> 6.7%
5. Patient present at pharmacy for more than 6 months

Participant type(s)
Patient

Age group
Adult

Lower age limit

18 Years

Sex
Both

Target number of participants
800

Key exclusion criteria
1. Cancer
2. Patients with insulin treatment or anti-diabetics injectables

Date of first enrolment
01/03/2014

Date of final enrolment
01/09/2016

Locations

Countries of recruitment
France

Study participating centre
PHARMACIE NGHIEM
France
91600

Study participating centre
PHARMACIE BONNET
France
34000

Study participating centre
PHARMACIE GOULET
France
76620

Study participating centre
PHARMACIE SUEUR
France
80230

Study participating centre
PHARMACIE HENRY
France
18120

Study participating centre
PHARMACIE BOUDON
France
15120

Study participating centre
PHARMACIE BERTHOLOM
France
29910

Study participating centre
PHARMACIE LAIR-MARTIN-LONGUESSERRE
France
31260

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PHARMACIE STAHL
France
88290

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PHARMACIE BERTOUX-FORESTIER
France
80134

Study participating centre
PHARMACIE BERA
France
38114

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PHARMACIE DERAM
France
62220

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PHARMACIE RENUCCI
France
84210

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PHARMACIE SCHAUB
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73230

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PHARMACIE GERMES-CANEPA
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PHARMACIE LAFORTUNE
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Study participating centre

PHARMACIE BIZON
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Study participating centre
PHARMACIE VAURY
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91670

Study participating centre
PHARMACIE THOUVEREY
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71500

Study participating centre
PHARMACIE MINGEAU
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58150

Study participating centre
PHARMACIE BOUTINET-DJILANI
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17650

Study participating centre
PHARMACIE VITOUX-GILLET
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59550

Study participating centre
PHARMACIE MOUTIER-DUMAS
France
87130

Study participating centre

PHARMACIE LEPINE
France
87220

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PHARMACIE DRIOUT
France
41500

Study participating centre
PHARMACIE TROUSSELLE
France
49000

Study participating centre
PHARMACIE TARODO DE LA FUENTE
France
81240

Study participating centre
PHARMACIE RAYMOND-TAUGOURDEAU
France
49112

Study participating centre
PHARMACIE BEGLIA JOEL
France
13200

Study participating centre
PHARMACIE SCHAUB
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73230

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PHARMACIE BREYSSE
France
81200

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PHARMACIE MALLIS
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62440

Study participating centre
PHARMACIE BONCHRISTIANI-ANDREANI
France
13013

Study participating centre
PHARMACIE BERGEZ-BEVALOT
France
25000

Study participating centre
PHARMACIE RODIER CABANIS
France
30420

Study participating centre
PHARMACIE DODIN-MOTTE
France
95290

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PHARMACIE DECLOITRE
France
33000

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PHARMACIE MILLERET-VERNAY
France
21250

Study participating centre
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45260

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31340

Study participating centre
PHARMACIE GIRARD-PLANTE-VIEITEZ
France
31660

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PHARMACIE LHOYER
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60160

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PHARMACIE SENEZ VANGHELUE
France
60840

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France
94370

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26000

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PHARMACIE DESERICOURT-PEREZ
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PHARMACIE KARAYAN
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60700

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PHARMACIE GUILLEBOT-VERGARA
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PHARMACIE FRANCK
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PHARMACIE BARBE - LECLERCQ
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PHARMACIE LESOIF-GRIMAULT
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Study participating centre
PHARMACIE BEGLIA JOEL
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Study participating centre
PHARMACIE MOUSSLY
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Study participating centre
PHARMACIE BOURDY-DUBOIS-CHANEL
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58640

Study participating centre
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France
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Study participating centre
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France
18120

Study participating centre
PHARMACIE COHARD
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Study participating centre

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Sponsor information

Organisation
Observia

Sponsor details
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laura.romengas@observia-group.com

Sponsor type
Research organisation

Organisation
MSD France

Sponsor details
34 Avenue Léonard de Vinci
Courbevoie
France
92400

Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
Merck

Alternative Name(s)

Merck & Co., Inc., Merck & Co.

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact reviewed journal.

Intention to publish date
31/12/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Laura Romengas (laura.romengas@observia-group.com).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2019	01/05/2020	Yes	No