Effectiveness of health microinsurance scheme in private primary care in Malaysia

Submission date	Recruitment status	[X] Prospectively registered
22/02/2016	No longer recruiting	[_] Protocol
Registration date	Overall study status	[] Statistical analysis plan
25/02/2016	Completed	[_] Results
Last Edited	Condition category	[_] Individual participant data
09/03/2016	Other	[_] Record updated in last year

Plain English summary of protocol

Background and study aims

Many people living in Malaysia are unable to access adequate healthcare. It is a growing problem, especially for families on a low income with children or a member suffering from a long-term (chronic) disease, such as diabetes or asthma. Despite healthcare services being available almost free of charge from the government, many citizens are still unable to be seen because of long waiting times and lack of specialized and personalized care. As a result of this, private healthcare clinics in which a patient needs to pay for healthcare (out-of-pocket financing, OOP) are becoming more common. This can be very difficult for those on a low income, as they may not be able to afford to get treatment as often as they need if they are suffering from a chronic disease. Microinsurance schemes are a type of financial protection for people on a low income, in which health insurance to low-income households in developing countries. The aim of this study is to find out whether a Health Microinsurance Scheme (HMI) at a private healthcare clinic is an effective way to encourage Malaysians to seek healthcare more often as needed.

Who can participate?

Members of households in Kuala Lumpur (Malaysia) that pay for their own medical care and have been seen in a participating private healthcare clinic within the last two years.

What does the study involve?

Fifty seven households who usually attend each of the two participating private healthcare clinics are randomly selected. Those who attend one clinic are given full access to the Health Microinsurance Scheme (HMI) for free for six months. This allows them to visit the healthcare clinic and use their services as much as they like within the six months. Those who attend the other clinic continue to seek treatment in the normal way, paying for the healthcare services they used (out-of-pocket). At the start of the study and then again after six months, the head of each household completes a number of questionnaires in order to assess how much they have used healthcare services in the last six months.

What are the possible benefits and risks of participating? Not provided at time of registration. Where is the study run from? 1. Klinik Suria (Malaysia) 2. Klinik Mediprima (Malaysia)

When is the study starting and how long is it expected to run for? December 2015 to December 2016

Who is funding the study? Chulalongkorn University (Thailand)

Who is the main contact? Dr Murallitharan Munisamy Murallitharan.M@student.chula.ac.th

Contact information

Type(s) Scientific

Contact name Dr Murallitharan Munisamy

Contact details

College of Public Health Sciences Institute Building 3 (10th – 11th floor) Chulalongkorn Soi 62 Phyathai Road Bangkok Thailand 10330 +66 2 218 8193 Murallitharan.M@student.chula.ac.th

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers NMRR 29311

Study information

Scientific Title

Effectiveness of a health microinsurance scheme in improving health equity and clinical outcomes for private primary care in Kuala Lumpur, Malaysia

Study objectives

A Health Microinsurance Scheme (HMI) is more effective compared to Out-of-Pocket (OOP) payments in improving health equity and clinical outcomes for private primary care clinics in Kuala Lumpur, Malaysia.

Ethics approval required

Old ethics approval format

Ethics approval(s) Malaysian Research Ethics Committee, Ministry of Health Malaysia, 04/03/2016, ref: NMRR-16-172-29311(IIR)

Study design Multi-centre quasi-experimental two arm pre-post intervention trial

Primary study design Interventional

Secondary study design

Randomised parallel trial

Study setting(s)

GP practice

Study type(s)

Other

Participant information sheet

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

Health condition(s) or problem(s) studied

Financing primary healthcare

Interventions

From each clinic, the list of patients who pay Out-Of-Pocket for consultation/treatment (current practice in Private Primary Care clinics in Malaysia) are compiled by family. These are patients who are already regular clients of these clinics and no outside populations are being recruited. Fifty seven households are then randomly selected from each clinic. Once the heads of the households provide informed consent, all participants answer a detailed questionnaire to capture their health-seeking behaviour, monthly health expenditure and through patient records at the clinic, capture changes in clinical outcomes for those with chronic disease. Participants attending one clinic take part in the Health Microinsurance Scheme (HMI) and those attending the other take part in a control arm.

Health Microinsurance Scheme (HMI) - Participants are provided with a fully-paid Health Microinsurance Scheme for 6 months. This scheme covers all their treatment and consultation costs, including drugs at the experimental clinic site. Participants are allowed to visit and receive all treatment and services at the clinic as and when they require it. Control - Patients visiting the control clinic are also free to visit and receive all treatment and services at the clinic as and when they require it, but will pay for it as per usual prices without any change.

After six months, the questionnaire completed at baseline is repeated for all participants.

Intervention Type

Mixed

Primary outcome measure

Health-seeking behaviour is measured as the delay in seeking care in days at baseline and 6 months.

Secondary outcome measures

1. Monthly household health expenditure is measured using the self-estimated in Ringgit Malaysia (RM) at baseline and 6 months

2. Quantifiable validated results for chronic diseases (such as HbA1c for DM, mean resting blood pressure for hypertension, Total serum cholesterol and LDL for dyslipidemia, spirometry for Bronchial Asthma) are recorded at baseline and 6 months

Overall study start date

01/12/2015

Completion date

31/12/2016

Eligibility

Key inclusion criteria

1. Households were located in the study area

- 2. Method of payment to clinic is by out-of-pocket
- 3. Members of the household's regular choice of primary care provider

4. Patient has been seen in the clinic within the past two years

provided with a fully-paid Health Microinsurance Scheme for 6 months. This scheme covers all their treatment and consultation costs, including drugs at the experimental clinic site. Participants are allowed to visit and receive all treatment and services at the clinic as and when they require it.

Participant type(s)

Patient

Age group

Adult

Sex Both

Target number of participants

There will be 57 households in each arm with 114 households to be included in the two arms. With expected a minimum of 3 people per household, it is estimated that there will be 342 participants in the trial.

Key exclusion criteria

1. Households with members who died in the year 2014

2. Households with members who were away from this place of residence for work/transferred for more than 1 month in 2014

3. Households with members who had regular follow-up in public facilities for chronic disease 4. Households with members who have switched methods of payment in the last year (e.g. newly bought insurance or retired and lost health benefits so paying OOP) 5. Patients who refuse consent

Date of first enrolment 01/04/2016

Date of final enrolment

01/06/2016

Locations

Countries of recruitment Malaysia

Study participating centre Klinik Suria Jalan Ipoh Kuala Lumpur Malaysia 51200

Study participating centre Klinik Mediprima Jalan Ipoh Kuala Lumpur Malaysia 51200

Sponsor information

Organisation Chulalongkorn University

Sponsor details

College of Public Health Sciences Chulalongkorn University Institute Building 2-3 Soi Chulalongkorn 62 Bangkok Thailand 10330 +66 2218 8193 academic_cphs@chula.ac.th

Sponsor type University/education

Website http://www.cphs.chula.ac.th/

ROR https://ror.org/028wp3y58

Funder(s)

Funder type University/education

Funder Name Chulalongkorn University

Alternative Name(s) , CU, Chula

Funding Body Type Government organisation

Funding Body Subtype Universities (academic only)

Location Thailand

Results and Publications

Publication and dissemination plan

Planned publication of at least four papers in a peer reviewed journal involving:

- 1. Baseline results of trial economics
- 2. Total results of trial -economics

3. Total results of trial - clinical outcomes

4. Policy paper

Intention to publish date

31/03/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Data sharing statement to be made available at a later date