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Community health workers for primary healthcare access

Submission date 23/10/2024	**Recruitment status** No longer recruiting	☒ Prospectively registered
		☐ Protocol
Registration date 23/10/2024	**Overall study status** Ongoing	☐ Statistical analysis plan
		☐ Results
Last Edited 24/06/2025	**Condition category** Other	☐ Individual participant data
		☒ Record updated in last year

Plain English summary of protocol

Background and study aims
In Belgium, research has demonstrated that people with difficulties accessing primary healthcare (PDAP) predominantly comprise people who live with socio-economic difficulties and /or people with low educational attainment. PDAP are often most in need of care, but amongst the least likely to receive it, leading to adverse health outcomes and increased costs. Despite the fact that various mechanisms have been implemented in the Belgian healthcare system to improve access to care for PDAP, inequality in access to primary health care (PHC) is increasing in Belgium, in contrast to the overall decreasing trend in the European Union. Innovation is needed to improve access to care for PDAP. As such, the current Belgium PHC model requires innovation that goes beyond the physical environment of General Practitioner (GP) practices and actively reaches out to PDAP. To respond to these needs, this study aims to develop a solution for the access-to-care challenges for PDAP in Belgium by learning from the Community Health Worker (CHW) model in the Family Health Strategy (Brazil) and Re-engineering PHC (South Africa) in line with reverse innovation. The Community Health Workers for Primary Healthcare Access (COMPASS) project will address these knowledge gaps by designing, implementing and evaluating to what extent and in what way access to PHC can be improved through a CHW intervention for people living in socio-economically vulnerable circumstances.

Who can participate?
Adults (minimum age of 18 years) who are part of the patient registry of the participating GP practices and were listed by the GP practice as patients who could benefit from additional support to better address a health need or health risk.

What does the study involve?
Participants are randomly allocated into two groups: those receiving standard of care, without additional support; and those receiving standard of care plus the CHW intervention to improve access to PHC. People in the intervention group will receive CHW support over the course of 12 months. Through monthly home visits, the CHW will build trust with their individual client and gain insight into their health situation, their personal goals around health and the barriers they experience to achieving them. Through an empowering approach the CHW aims to address these barriers, giving people more control over their health in the long term. After a first introductory visit (step 1) in the first month in which the CHW and client get to know each other,

the CHW will deliver the core components of the intervention over the course of the next 10 months. In this second step, five blocks are identified that the CHW will focus on – at the pace of the client: (block 1) household assessment; (block 2) personal goal setting and action plan; (block 3) getting the client acquainted with the healthcare landscape; (block 4) social integration both professional and informal network/links; (block 5) engaging in prevention and mental health. In the last visit at 12 months the CHW has a concluding session (step 3) with the client to make a plan in which way the client will take care of his or her own health towards the future.
Self-rated health, health care use, health-related quality of life, consultation appropriateness, health literacy, empowerment, and the financial burden of health care are all measured.

What are the possible benefits and risks of participating?
Participants can gain from improved access to healthcare as well as improved self-perceived health. Participants may inadvertently feel pressured to engage with healthcare services and healthcare professionals and therefore experience further demotivation.

Where is the study run from?
University of Antwerp and the University of Gent (Belgium)

When is the study starting and how long is it expected to run for?
January 2023 to December 2026

Who is funding the study?
The Research Foundation - Flanders (Belgium) under the Strategic Basic Research Projects

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Leaving no one behind: bridge the gap between vulnerable populations and the primary healthcare system through 'reverse innovation'

Acronym
COMPASS

Study objectives
Sustainable Development Goal 3 underlines the right of everyone to have timely access to primary healthcare (PHC). Despite the fact that Belgium has put various reforms in place to make PHC more affordable and accessible, inequalities in access to care are even getting bigger – creating the need for innovative measures. A new healthcare model should thus be designed and tested to link people who have difficulties accessing PHC (PDAP) to the existing PHC system.

Such a new model requires new fundamental knowledge, as former solutions have repeatedly failed. Since the country is also confronted with increasing health demands and limited budgets, there is impetus to tap into the potential of reverse innovations from low and middle-income countries (LIMCs). A review of health innovations in LIMCs and a theoretical analysis of the required characteristics of such a new model resulted in a community health worker (CHW) intervention – inspired by the Family Health System in Brazil and Re-engineering PHC in South Africa. It is hypothesised that an outreaching PHC model with a CHW intervention will address the access-to-care challenges in Flanders, Belgium.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 19/06/2024, Ethics Committee for the Social Sciences and Humanities (EA SHW) (Sint Jacobstraat 2, Antwerpen, 2000, Belgium; +32 (0)3 265 90 63; eashw@uantwerpen.be), ref: SHW_2024_126

Study design

Cluster randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention, Quality of life

Health condition(s) or problem(s) studied
Access to primary care for people living in socio-economically vulnerable circumstances

Interventions
The primary activity for the COMPASS study will be the implementation and assessment of the impact of a CHW intervention in a cluster randomised controlled trial (cluster RCT) with two arms:
1. Those receiving standard of care, without additional support
2. Those receiving standard of care plus the CHW intervention to improve access to PHC

The randomization process was done using a simple randomization technique, based on computer-generated random numbers and considering the stratification for the type of GP practice (fee-for-service and forfaitair clinics). By stratifying the clinics into two groups based on GP practice type, the researchers ensure that any differences between the clinic types are balanced between the intervention and control arms.

Through monthly home visits, the CHW will build trust with their individual client and gain insight into their health situation, their personal goals around health and the barriers they experience to achieving them. Through an empowering approach, the CHW aims to address these barriers – allowing to give people more control over their health in the long term. After a first introductory visit (step 1) in the 1st month in which the CHW and client get to know each other, the CHW will deliver the core components of the intervention over the course of the next 10 months. In this second step, five blocks are identified that the CHW will focus on – at the pace of the client: (block 1) household assessment; (block 2) personal goal setting and action plan; (block 3) getting the client acquainted with the healthcare landscape; (block 4) social integration both professional and informal network/links; (block 5) engaging in prevention and mental health. In the last visit – the 12th month – the CHW has a concluding session (step 3) with the client to make a plan in which way the client will take care of his or her own health towards the future.

Intervention Type
Behavioural

Primary outcome(s)
Self-rated health, as measured by the first question of the Short Form 12 Health Survey: “How do you rate your own health over the last year?” on a five-point Likert scale and by the Visual Analog Scale of the EuroQOL (Range 1–100), measured at baseline, 6 and 12 months

Key secondary outcome(s))
1. Health care use measured using the Medical Consumption Questionnaire (iMCQ) measured at baseline, 6 and 12 months
2. Health-related quality of life measured using EQ-5D-5L at baseline and 12 months
3. Health literacy measured using HLS-EU-Q6 at baseline and 12 months

4. Empowerment measured using the Client Empowerment in Community Health Systems Scale at baseline and 12 months
5. Financial burden of health care measured using the Health Interview Survey, Sciensano at baseline and 12 months

Completion date
31/12/2026

Eligibility

Key inclusion criteria
1. Minimum age of 18 years
2. Part of the patient registry of the participating GP practices
3. Listed by the GP practice as patients who could benefit from additional support to better address a health need or health risk

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
368

Key exclusion criteria
1. Individuals who received already support from CHWs as part of the Federal CHW program
2. Individuals who will not be able to give consent for any reason, such as severe mental health disorders

Date of first enrolment
04/11/2024

Date of final enrolment
11/06/2025

Locations

Countries of recruitment
Belgium

Study participating centre
18 participating General Practitioner (GP) practices in the wider region of a city in the North of Belgium
Belgium
2000

Sponsor information

Organisation
University of Antwerp

ROR
https://ror.org/008x57b05

Funder(s)

Funder type
Government

Funder Name
Fonds Wetenschappelijk Onderzoek

Alternative Name(s)
Research Foundation Flanders, Flemish Research Foundation, Research Foundation – Flanders, Fonds voor Wetenschappelijk Onderzoek - Vlaanderen, The FWO, Het FWO, FWO

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Belgium

Results and Publications

Individual participant data (IPD) sharing plan
Data will not be made publicly available but can be made available upon reasonable request from the authors

IPD sharing plan summary

Available on request, Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes