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Scale up diabetes and hypertension care for vulnerable people in Cambodia, Slovenia and Belgium

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Registration date 03/02/2020	**Overall study status** Completed	
Last Edited 19/08/2024	**Condition category** Other	

Plain English summary of protocol

Background and study aims
Many countries struggle with how to scale-up interventions for chronic care and self-management support effectively and sustainably. This proposal addresses that gap, by examining the scale-up of existing evidence-based interventions for the control of hypertension (HT) and/or Type 2 Diabetes (T2D). The main objectives are:
1) To analyse the organisational capacity to scale-up integrated care for HT and T2D in Belgium, Slovenia and Cambodia and to assess contextual barriers and facilitators to doing so
2) To develop and implement roadmaps for a national scale-up strategy in each country
3) To evaluate the impact on health outcomes and efficiency of care through the scale-up of the ICP
4) To generate lessons across contexts on the scale-up strategies for integrated care for HT and T2D

Who can participate?
All people with TD2 and/or HT are eligible to benefit from the scale-up of the ICP: it is a process of natural experimentation so the research design does not have exclusion criteria for people to benefit from the intervention. In Belgium and Slovenia, the researchers will specifically develop interventions to benefit vulnerable people with HT and/or T2D, the definition of vulnerable being over 65 years old or having multi-morbidity

What does the study involve?
The proposal considers each country as a case study for the scale-up of the Integrated Care Package (ICP) for T2D and HT. The study has a 1-year informative phase, a 1-2 year implementation phase (years 2-3) and a final 1-year evaluation phase. In the first phase of the study, the researchers will examine the present small-scale implementation of the ICP in each country. This will include the assessment of the capacity of the organisations involved and of the contextual facilitator and barriers for scale-up. The researchers will assess the current strategies in place for implementation, defined as the starting point. The implementation phase (years 2-3) includes the development and deployment of an improved scale-up strategy through a roadmap with actions to operationalise scale-up in each country. The roadmap includes organisation and

stakeholder engagement, and processes to ensure financing and monitoring. Since the country contexts and initial scale-up strategies are different, three roadmaps will be developed. The progress of each roadmap will be evaluated using a common framework. In the fourth year, the implementation and impacts of the optimised scale-up strategies will be evaluated.
At the core is an Integrated Care Package (ICP) with five components: (a) identification of people with HT and/or T2D and subsequent (b) treatment in primary care services, (c) health education and (d) self-management support to patients and caregivers, and (e) collaboration between caregivers. The proposal develops, implements and assesses roadmaps for the scale-up of the ICP for T2D and HT, in three different types of countries, a low-middle income country with a developing health system, a former socialist high-income country with a centralised health system, and a Western European federal country with a decentralized system.
The evaluation will comprise of an in-depth process evaluation of the roadmap in each country and an outcome evaluation that assesses the differences in outcome measure before and after the scale-up (quasi-experimental design). The process evaluation analyses how the reality of scale-up adheres to the developed roadmaps and how the different contexts can influence the implementation process of the scale-up strategies and will be based upon the implementation fidelity framework. The implementation of scale-up will be evaluated according to the three dimensions of scale-up: (a) the population coverage of the ICP, and (b) the expansion of the intervention package towards the ICP and (c) the integration of the intervention into the larger health system. A cost evaluation will be done after two years of scaling-up implementation. At the end of the implementation process, the research teams will evaluate the impact of the scaling-up of the ICP on the control of T2D and HT. The impact evaluation will assess the indicators relating to health outcomes and patient-centeredness. The impact will be assessed for each country separately, after which a cross-country comparison will be possible through the common dataset developed.

What are the possible benefits and risks of participating?
These roadmaps will accelerate scale-up and contribute to sustainable coverage of T2D and HT interventions for more people in each country. The implementation and evaluation of the three roadmaps, one per country, will generate new knowledge on how to scale-up integrated care for T2D and HT in diverse contexts. The benefits for people (vulnerable groups, patients with HT and /or T2D) in participating might be the improved Integrated Care Package they receive.
Scale-up interventions are complex interventions and it is difficult to predict the effect of scale-up of integrated care for T2D and HT on other parts of the health system, for instance on patients with other diseases. Unintended consequences of the scale-up strategies will be carefully monitored, through the two-way feedback system with implementing organisations and observations of the context. The interventions are meant to address their needs better. Only the research team and associated members will have access to the data.
The focus on vulnerable populations in Slovenia and Belgium could potentially increase stigma. The linkage with implementing organizations and the strategies for the respect of the target population are meant to counteract this tendency. The outcomes of the scale-up aim to create care better addressing their needs. In that way, the population in the study will benefit directly from the study. The data collected and synthesized will be fed back to scale-up services for chronic diseases. In addition, the researchers aim to improve social accountability. Empowerment of the population and community involvement are an integral part of the study.
In the household survey in Cambodia, physical measurements and blood samples will be collected from the participants. This will be done following standard procedures of Good Clinical Practice, ensuring hygiene and infection risk. Therefore, the risk is considered minimum. In the other countries, no physical measurements will be taken; routine clinical monitoring data will be used; The main risk to patients might be their loss of privacy. The researchers have elaborated procedures following the GDPR regulations to ensure consent and protect the privacy of patients and of other participants in the study.

Where is the study run from?
Coordinating institute: Institute of Tropical Medicine Belgium. Consortium of five partner institutions, implementation in three countries (Belgium, Slovenia, Cambodia)

When is the study starting and how long is it expected to run for?
January 2019 to June 2023

Who is funding the study?
EU Horizon 2020

Who is the main contact?
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Scientific

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Additional identifiers

Protocol serial number
H2020 grant 825432

Study information

Scientific Title
Scale up an integrated chronic care package for diabetes and hypertension for vulnerable people in Cambodia, Slovenia and Belgium

Acronym
SCUBY

Study objectives
The SCUBY project seeks to scale-up a common ICP in three different contexts. It is built upon the purposeful selection of three countries with different health systems: 1) a high income federated system in Belgium; 2) a transitional formerly central command health system in Slovenia and; 3) a middle income developing health system in Cambodia. The countries differ in terms of the stage of epidemiological transition, health system and health policy, resource availability and socio-economic and political attributes. Our start hypothesis is that - rooted in their societal and health system's context - these countries have adopted distinct scale-up strategies for the ICP for T2D and HT: control– horizontal (Belgium), vertical (Cambodia) and diversification (Slovenia).
The research project allows us to understand what enables the scale-up of the ICP for T2D and HT in different types of settings and to develop and test multiple strategies that can be adapted for replication in various health care systems.
The project will lead to lessons on optimal adaptions, choice, implementation and impact of scale-up strategies with relevance for other contexts.

The specific research objectives are:
1. To analyse the organisational capacity to scale-up integrated care for HT and T2D in Belgium, Slovenia and Cambodia and to assess contextual barriers and facilitators to do so
2. To develop and implement roadmaps for a national scale-up strategy in each country.
3. To evaluate the impact on health outcomes and efficiency of care through the scale-up of the ICP.
4. To generate lessons across contexts on the scale-up strategies for integrated care for HT and T2D.

The proposed research has three phases:
Phase 1: analyse the current context to assess bottlenecks within the health system for implementation of the evidence-based care package.
Phase 2: devise and implement a roadmap for each country – sensitive to the current scaling-up strategies – to move towards a comprehensive scaling-up of the ICP for treatment.
Phase 3: evaluate the process and impact of these roadmaps for scaling-up.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 16/09/2019, Institutional Review Board Institute of Tropical Medicine (Institute of Tropical Medicine - Nationalestraat 155, 2000 Antwerp, Belgium), ref: 1323/19
2. Approved 08/04/2019 and 05/08/2019, Ethical Committee University of Antwerp (Universiteit

Antwerpen, Comite voor medische ethiek, UZA, Wilrijkstraat 10, 2650 Edegem; Tel: +32 (0)3 821 30 00; Email: ethisch.comite@uza.be), ref: B300201940005, B300201941020
3. Approved 26/04/2019, National Ethics Committee for Health Research (Samdach Penn Nouth Blvd 289, Sangkat Boeungkok2, Kan Tuol Kork, Phnom Penh, Cambodia; Tel: +855 (012) 842 442; +855 (012) 528 789; +855 (012) 203 382; Email: not provided), ref: 115
4. Approved 24/05/2019, National Ethics Committee Slovenia (Komisija Republike Slovenije za medicinsko etiko, Stefanova ulica 5, 1000 Ljubljana; Tel: +386 (0)1 478 60 01; +386 (0)1 478 69 13; Email: gp.mz@gov.si; kme.mz@gov.si), ref: 0120-219/2019/4

Primary study design
Observational

Study design
Natural experimental design with interrupted time series measurements and scale-up interventions that will follow a stepped-wedge implementation process

Study type(s)
Other

Health condition(s) or problem(s) studied
Type 2 diabetes and hypertension

Interventions
The intervention is not yet established, since this will be done through policy dialogues based upon the formative findings. The focus of the intervention will be the development and deployment of an improved scale-up strategy, through a roadmap with actions to operationalise scale-up in each country.

Examples of the interventions that will be considered are:
1. Actions to increase population coverage, expand the intervention package and increase integration
2. Protocols and flow charts, education materials, self-management support tools for patients and caregivers, equipment, materials and medicines, patient records allowing for longitudinal follow-up, and guidelines on collaboration with specialised medical services, pharmacies, social care services, and patients
3. Involvement of patients, informal caregivers and community groups
4. Training of staff in primary care centres, training of educators and people involved in self-management support, supervision of people and informing patients and their caregivers about the changes
5. Task shifting; improving referral pathways to second-line services, organisations for education and self-management support; appointment systems between different actors and patients; the development of better communication channels
6. Monitoring of individual patients through a medical record system and monitoring at organisational level through a health information system
7. Designing financing structures that allow reasonable payment to providers, and stimulate teamwork and collaboration between different sectors at reasonable cost for patients

The scope of this project is to contribute to scale-up at the national level in each country. The theoretical eligible people for the ICP are for each country:
Cambodia: 15 million inhabitants with according to rough estimates 11 % diabetes and 25% hypertension. The current scale-up plans of the government are to expand geographical

coverage of the ICP towards 60 out of 159 operational districts (38% roughly approximating 5,7 million people). Assuming similar diabetes and hypertension prevalence, this could potentially be 627,000 people with T2D and 1.4 million people with HT
Slovenia: an estimated 184,000 inhabitants have T2D. The scale-up plan is to expand the ICP with additional elements in the communities, throughout the whole country. Theoretically, this makes all 184,000 inhabitants eligible. The researchers will focus on the vulnerable people, being those above 65 and those with multi-morbidity (numbers yet unknown)
Belgium: An estimated 621,000 people have T2D. The scale-up plan is to integrate the ICP better in the health system, focusing also on collaborating with other sectors and better implementation of the care pathways. Theoretically, this makes all 621,000 inhabitants eligible. The researchers will focus on the vulnerable people, being those above 65 and those with multi-morbidity (numbers yet unknown)

Total duration of follow-up: 2 years. The researchers will observe with interrupted time series, at least annually.

Intervention Type
Mixed

Primary outcome(s)
The impact evaluation will assess indicators relating to health outcomes and patient-centeredness. These data will be collected for all known T2D and HT patients subscribed to a facility in the areas where scale-up is taking place. There will be at least two measurements: the start of scale-up (beginning of year 2 or any later phase, depending on the phasing of scale-up) and at the end of year 3, preferably more interrupted time series. The difference in time of follow-up will be accounted for in the analyses.
The core health outcomes identified are:

For T2D :
1. Number of people with T2D: measured by prevalence of year x-1
2. % of people tested for T2D: number of people tested over a certain period
3. % of people diagnosed in year x-1
4. % of people retained in care in year x (past year)
5. % of people being on treatment in year x
6. % of people with good T2D outcomes in year x

For hypertension:
1. Number of people with HT: measured by prevalence of year x-1
2. % of people tested for HT: number of people tested over a certain period
3. % of people diagnosed in year x-1
4. % of people linked and retained in care in year x (past year)
5. % of people being on treatment in year x (medication)
6. % of people followed up in year x
7. % of people with good HT outcomes in year x

Key secondary outcome(s)
Apart from the impact evaluation (see primary outcome measures), the researchers will do a process evaluation and implementation evaluation, and a cost evaluation of the scale-up process.

1. Reach: number of scaleable units covered by the scale-up, measured using project documents on implementation at baseline and endline

2. Acceptability and feasibility of the scale-up strategy, measured using interviews with stakeholders and participants and questionnaire items to participants included in the follow-up measurements at endline
3. Adaptation of the scale-up strategy, measured using project documents on implementation (continuous)
4. Fidelity of implementation, measured using interviews with stakeholders and observations of work practices at endline

The implementation evaluation will cover three dimensions of scale-up:
1. The population coverage: indicators mentioned above / measured at the population level, measured by number of scaleable units covered, by target population living in the area, and (potential) by number of people actually covered by the intervention. Measured at baseline and endline
2. The expansion of the intervention package towards the ICP: number of components added to the ICP, measured at baseline and endline
3. The integration of the intervention into the larger health system. This will be measured at the system level by the presence of sustainable financing arrangements for the ICP, provider payment mechanisms that stimulate health education and self-management, human resource planning for teamwork in facilities and with community, the development of guidelines or care pathways and the development of common monitoring. These measures will be collected through project documents and key informant interviews at endline. The integration at operational level will be measured at operational level using normalisation process theory. The following elements are proposed to be measured at operational (meso-) level: the level of collection action needed at the level of an organisation (GP practice, operational district, chronic care team that is implementing the ICP) measured by the following questions (How will the intervention affect the work of user groups? Will staff require extensive training before they can start? How compatible is it with existing work practices? What impact will it have on the division of labour, resources, power, and responsibility between different professional groups? Will it fit with the overall goals and activity of the organisation?). Measured at endline

1. The cost evaluation: data will be collected on the cost, the human resources, and service delivery arrangements of the s-u actions, through primary qualitative data in a series of consultative workshops during the scale-up interventions
2. Secondary qualitative data on the strengths and weaknesses of the current health financing arrangements will be collected at baseline
3. Secondary quantitative baseline data on health services statistics and cost data collected through the above studies at baseline and endline

Completion date
30/06/2023

Eligibility

Key inclusion criteria
The scale-up in Cambodia targets the people using public health services, and in Slovenia and Belgium, the scale-up focuses on vulnerable people. In practice, this will include people who are of old age with multiple morbidities.

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
There are no exclusion criteria

Date of first enrolment
01/09/2020

Date of final enrolment
30/06/2022

Locations

Countries of recruitment
Belgium

Cambodia

Slovenia

Study participating centre
Population-based study so all public health facilities in the countries are potentially participating centers.
Belgium
1000

Study participating centre
Population-based study so all public health facilities in the countries are potentially participating centers.
Cambodia
12100

Study participating centre
Population-based study so all public health facilities in the countries are potentially participating centers.
Slovenia
1500

Sponsor information

Organisation
Horizon 2020 programme of the European Union

Funder(s)

Funder type
Government

Funder Name
Horizon 2020 Framework Programme

Alternative Name(s)
EU Framework Programme for Research and Innovation H2020, Horizon 2020, Horizon 2020 Framework Programme (H2020), Rahmenprogramm Horizont 2020, Horizont 2020, Programa Marco Horizonte 2020, Horizonte 2020, Programme-cadre Horizon 2020, Orizzonte 2020, Programma quadro Orizzonte 2020, H2020

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request. A managed access procedure will be developed to allow access to other researchers that wish to use the study data for secondary analysis after the closure of the study. These data will not be made openly accessible in line with national, European and international legal, ethical and privacy concerns. Access to the data will be controlled by the SCUBY Steering Committee, according to the procedures specified in the Consortium Agreement. After the study has been completed and the main study paper published, then researchers can apply to the Steering Committee with proposals to access the study dataset for future studies. Access to the dataset requires approval from the Steering Committee, which comprises representatives from each consortium partner (work package leaders) and is chaired by the Project Coordinator (via project manager smenon@itg.be). Researchers will additionally need to sign a Data Sharing Agreement to protect the integrity and confidentiality of the requested data. Any shared data will be further minimised and anonymised as possible for the requested purpose. Further details are available in a Data Management Plan.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Cambodia	22/06/2023	23/06/2023	Yes	No
Results article	Slovenia	15/08/2024	19/08/2024	Yes	No
Protocol article	Study design	31/12/2020	29/06/2021	Yes	No
Protocol article		02/09/2022	05/09/2022	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes