Pursuing the Tiple Aim in Hotspotters:identification and integrated care

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Objective: Is proactive integrated care costeffective and does it result in better patients experience than usual care after 12 months for patients with problems on multiple life domains?This study will focus on measuring the changes in the...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON54393

Source
ToetsingOnline

Brief title
The Hotspotters Project

Condition

- Other condition
- Economic and housing issues

Synonym
Problems on multiple domains, vulnerable persons.

Health condition

Multi-morbiditeit (psychisch, sociaal en somatisch)

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: High cost patients, Multiproblem approach, Patient experience

Outcome measures

Primary outcome

The main study parameter is incremental cost-effectiveness. To measure this outcome data sources will be used and linked at the individual level. At the start of the study (t=0) and at the end (t=22) data on care usage and costs will be collected. These data will be translated into cost using standard cost prices from the Dutch guideline for economic evaluations.

Secondary outcome

1.Patient experience of care

The secondary study parameter is insight into the patient experience of care. To assess their experience focus groups will be organized. Four main topics will be discussed, namely: care before the new approach, the new approach, the collaboration between the professionals and the experienced effects of the new approach. Furthermore, information about self-efficacy (PAM-13 and SE+IN itemlist), proactive coping (UPCC), and quality of life (SF-12) will be collected using questionnaires

2.Process evaluation

A process evaluation of this study will be done simultaneously, as a process

evaluation can provide valuable insight on the practicalities of the intervention. Data on recruitment and reach of the population will be gathered during the inclusion of patiens in this study. Information on integration of care with the social domain and the mental domain will also be gathered. Additional questionnaires will be gathered about patient satisfaction with care, using a modified version of the NPS (Reichheld, 2003). The nature of the communication between care professional and patient, will be assessed using a HCCQ questionnaire (Jochems, Duivenvoorden, van der Feltz-Cornelis, & van Dam, 2014; Czajkowska, Wang, Hall, Sewitch, & Körner, 2017). Furthermore, a questionnaire will be used combining the assessment of the acceptability (Acceptability of Intervention Measure - AIM), appropriateness (Intervention Appropriateness Measure - IAM), feasibility (Feasibility of Intervention Measure - FIM), and perceived and experienced effectiveness of the intervention (Weiner, Lewis, & Stanick, 2017).

Study description

Background summary

Hotspotters have complex problems on multiple life domains, treated with expensive fragmented care which is difficult to manage by patients and care providers, leading to little effect of the care and persistent unmet needs. The accumulation of problems within hotspotters is related to high medical expenses. Next to their high medical spending levels, hotspotters experiences with the healthcare system are low as the healthcare system is not (yet) successful in dealing with their needs. This group places a lot of strain on healthcare professionals since their problems require a multidisciplinary supply of healthcare services, often in combination with social care and welfare. The term *hotspotters *was first introduced in Gawande*s landmark article. He suggested that the accumulation of problems and high hospital costs were concentrated in certain areas (also defined as *hot spots*) in Camden, New

Jersey. When looking at medical care data he noticed that there was a small group of people located in these areas, who accounted for most of the medical costs. Up until now, a proper evaluations of the treatment (proactive integrated care) in the *hotspotter* group yield undecisive conclusions. Interventions aimed at the complex situation of hotspotters in our current healthcare system might benefit by applying The Triple Aim approach. This approach aims to improve the individual experience of care, reduce the cost of care per capita and improve the health of populations.

Study objective

Objective: Is proactive integrated care costeffective and does it result in better patients experience than usual care after 12 months for patients with problems on multiple life domains?

This study will focus on measuring the changes in the following:
1. Incremental cost-effectiveness from a societal perspective. Information on cost will be based on patient-reported data obtained by questionnaires supplied with data from the GP medical files (Huisarts informatie system, HIS) and CBSmicrodata. To assess the effectiveness the EQ-5D-5L will be used for determining quality of life.

The secondary study parameters are:
1. Insight into patients experience of care, quality of life, proactive coping, and self-efficacy. This information will be gathered using interviews, focus groups and questionnaires (SF-12, UPCC, PAM-13 & Self-efficacy and Intentie itemlist).
2. Process evaluation with the involved care professionals, including the integration level of care per GP-practice, the nature of the communication between healthcare provider and patient (HCCQ, OPTION5), and acceptability (AIM), appropriateness (IAM), feasibility (FIM) ,and perceived and experienced effectiveness of the intervention.

Study design

We will use a stepped-wedge randomised controlled trial (RCT) design (Hemming, Haines, Chilton, Girling ,& Lilford, 2015). This design involves random and sequential crossover of groups from control to intervention until all groups are exposed to the intervention. A stepped wedge cluster RCT is especially useful when the intervention is thought to do more good than harm (i.e.,when there is no equipoise). In that situation, it is unethical to withhold or withdraw the intervention from a proportion of the subjects as would occur in a parallel group or classic cluster RCT. Besides, it may be impossible to implement the intervention in half of all clusters simultaneously because of

practical, logistical, or financial reasons, which is also the case in the current study with regard to the practical and logistical reasons. Then, the stepwise treatment implementation of the stepped wedge design offers a solution. Since all patients included in this study will be offered the intervention, which may contribute to limiting lost to follow-up
The personalized approach, local collaborations with the social domain and organizational differences between general practices will result in nuanced differences in how our intervention will be applied. Besides, training the Positive Health methodology and the enhanced collaboration between domains most likely effects patients not-offered the intervention as well. Randomisation will therefore be done by cluster.
This study will be performed in 20 general practices. Each practice will form one cluster. We aim to include an average of 10 patients per cluster. A GP or POH-GGZ can only participate in one cluster. The terms GP practice and cluster will be used alternatively and exchangeable form this point on, both referring to the given description.
Each participating patient starts with a control period and will cross-over to the intervention period. The control period varies between 2 to 8 months. All patients from a GP practice cross-over at the same moment. Therefore the GP-practices are randomized into one of four groups.
All clusters start to collect control data at the same time (t=0). The 20 clusters will be divided into four groups evenly and each group will be randomly assigned one of four time points at which they will start to implement the proactive integrated care intervention. The first switch will be after 2 months (t=2). Every subsequent 2 months a next group of general practices will switch to the intervention mode until all groups have started the intervention. All groups will continue with the intervention as described in this protocol for a total of 12 months. After the 12 months of intervention, care will be delivered as usual. There is no objection if care providers and patients wish to maintain certain aspects of the intervention. All measurements and timepoints after the switch to the intervention falls under the intervention period. The total duration of this study comprises 22 months. This results in varying control period ranging from 2 to 8 months. The total of intervention and follow-up period vary from 14 to 20 months. This time table is summarized in the following chart. In order to achieve more accurate answers from patients and in turn more reliable results, a member of the research team will administer the SF-12, and questionnaires on proactive coping (UPCC), and self-efficacy (PAM-13 and SE+IN) during a face to face interview, as these might require extra guidance when filling in. This will be done at three time points for each group (before the start of the intervention, at the end of the intervention, and two months after the intervention has ended).

Intervention

The proactive integrated care intervention that will be used consists of five steps:
1. Active invitation of the patient from the practice

2. Consult of 45 minutes with a trained Practice Nurse Mental Health Care based on the Positive Health Methodology. The outcome of this consultation is a spiderweb with an overview of current health status according to positive health methodology.
3. Multidisciplinary Team meeting (MDO) based on the spider web with the domain specific explanation. In this MDO at least the mental health practice nurse, GP, social worker or community nurse are present. The patient is always invited. The outcome of this meeting is: (1) a personalised care plan; (2) appointment of one care coordinator and (3) a structured follow up plan (frequency and duration) of the progression of this patient*s problems.
4. Execution of the personalised care plan. The care coordinator has frequent contact with the patient. A minimum of 3 consultations for the first 12 weeks is set, however more frequent consultation can be expected. The proactive nature of this contact is emphasized. A minimum of 4 consultations between patient and care coordinator is set.
5. Follow-up of the personalised care plan. During the regular monthly meetings of the health and social care network the follow-up of the patients will be reviewed. Each patient will be discussed at least two times, but more often if necessary. In case the care plan is not followed correctly or it does not have the desired outcome, the patient and

Study burden and risks

Participation in this study is expected to be low risk for the patients.
However, both risks and benefits are associated with participation.
Benefits include:
Improved knowledge and insight: Participation might lead patients to have a better understanding of the factors that contribute to their overall well-being. This can be achieved with analysing the six life domains of the positive health conversation tool. This insight might result in appropriate interventions that meet the needs of the hotspotters.

A potential risk that should be taken into account is:
(temporary) Elevated stress: hotspotters* experience a combination of different problems which can make life more complex and challenging. Participation could results in more stress in some participants (especially in the beginning) due to the heightened emphasis on the factors that contribute to their health and social problems.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

-The patients are >= 18yrs
-The patients are registered within one of the participating GP practices.
-Patients with at least two acute care encounters in the past 12 months. Acute care encounter is defined as an encounter with out-of-hours GP service, emergency care or acute mental health care.
-Patients have problems registered in the GP Information system on at least two out of three of the following domains: somatic, mental or social.

Exclusion criteria

- The patient is terminal.
- The patient is living in a residential home.
- The patient has dementia or a disability that prevents them from communicating effectively.
- The patients opt out for permission to use medical data
- The patient already has experience with the positive health tool.
- The patient is not competent to make decisions concerning their health. This

wil be assessed by the patient*s own general practitioner.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-08-2023
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	01-07-2022
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	29-08-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	04-05-2023
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	20-09-2024
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL78646.058.21