THE USE OF A MONITORING DEVICE BY GENERAL PRACTITIONERS DURING OUT-OF-HOURS CARE: PROTOCOL OF A PROSPECTIVE RANDOMIZED CONTROLLED TRIAL

Renier W[1], Sabbe M[2], Buntinx F[1,3], Verbakel JY[1,4]

[1] KU Leuven, Department of Public Health and Primary Care

[2] KU Leuven, Department of Emergency Medicine UZL, University Hospital Gasthuisberg

[3] Maastricht University CAPHRI School for Public Health and Primary Care, Research Institute Caphr

[4] University of Oxford, Nuffield Department of Primary Care Health Sciences

Corresponding address:

Dr. Walter Renier, ACHG, Kapucijnenvoer 7 Blok H, PB 7001 – 3000 Leuven

Email: walter.renier@gmail.com

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ABSTRACT

Background

During an urgent home visit, a general practitioner (GP) is typically multitasking while figuring out to what extent a patient needs referral. GPs' usual tools are not always sufficient. An accurate, portable monitoring device, fitting in a doctor's bag, capable of registering the same parameters and curves as the emergency department monitors, was selected. We aim to investigate if during emergency visits this device can improve GPs' decisions to refer a critically ill patient to hospital or not, whether the device improves clinical decision making, provides sufficient information and is easy to use during urgent home visit.

Methods

For this prospective randomized controlled trial, we aim to include 866 patients, ≥ 18 years old, contacting the out-of-hours GP services (OHGPS) via 112 or 1733, and subsequently visited by physicians from OHGPS. Once an informed consent is obtained, patients are included in one of two arms, with and without the use of the monitoring device. The GP records diagnosis, referral and parameters obtained from the device. At 30 days, patients' outcome is reviewed either from their regular GP's health record or in the hospital to which the patient was referred. We will compare diagnoses, referrals, investigate parameter, curves observed and the user-friendliness of the device and analyse quantitative and, after coding, qualitative data. The study was approved by the ethical committee of KU Leuven under the S-number S63046 on October 07 2020.

Discussion

Randomization will be stratified at the OHGPS level and by GP's intervention vehicle in blocks of six. Obtaining an informed consent is important because the study focusses on emergencies where extensive explanation of the study is often limited due to time constraints. Outcome data after 30 days will be requested from the regular GP and checked in the emergency department's electronic health record.

Keywords: out-of-hours general practice service, monitoring, emergencies, home visits, parameters, referral, outcome, (informed consent, randomisation).

INTRODUCTION

Calls to an out-of-hours general practitioner's service (OHGPS) for an emergency could originate from different types of callers. Based on the information provided over the phone, it is sometimes difficult to figure out to what extent the call can actually be considered urgent. General practitioners (GP) or their dispatchers frequently must rely on their own gut-feeling [1].

The development of the out-of-hours services by GPs in Belgium recently led to the introduction of a uniform urgent phone number 1733 for out-of-hours calls. The phone operator can send a GP for an urgent home-visit, ask the patient to go to the OHGPS, to wait until the next available appointment with his/her regular GP or go to the emergency department (ED) immediately [2]. To optimise use of medical workforce, a pilot project was set up, combining the above mentioned 1733 number with the 112 national emergency number, the regular emergency dispatch service. The 112 dispatcher can decide (I) to send the MET, (II) a PIT, similar to MET but without a doctor on board, (III) an ambulance, (IV) request the patient to go to the ED, or (V) send a message to the OHGPS dispatcher. The latter can decide upon the most suited approach. Not only the 112 dispatcher, but also the OHGPS phone operator must be able to differentiate an urgent situation from the vast majority of semi-urgent calls.

The assessment of an acutely ill patient relies on the clinical data observed and measured by GPs. For years, GPs measured blood pressure and pulse rate, observed heart rhythm and respiratory sounds. Over the last 50 years, a few additional technological advancements have facilitated early diagnosis: Electrocardiograms (ECG), thermometers and some point of care tests (POCT) such as urine dipsticks or blood glucose measurement. Only recently, POCTs were further introduced after a gap of nearly 30 years [3]. Some devices such as a portable pulse oximeter [4,5,6] and devices to document one-lead ECG recordings [7] were progressively introduced in routine daily care.

During an urgent home visit, a GP is typically multitasking: taking clinical history, performing clinical examination, formulating a diagnostic hypothesis, administering medication and also checking as many vital parameters as possible. There is hardly any time left to make notes. Consequently, GPs might forget to control the evolution over time of some parameters or, if checking parameters too frequently, to monitor the patient appropriately.

Monitoring of parameters by pulse oximetry, is very helpful to alarm the physician whenever something goes wrong. Generally, GPs do not have a monitoring device similar to the one EPs carry. Most research focused on monitoring chronic diseases (e.g. diabetes, renal failure), assessing a patient with pulse oximetry [3,8,9] or event monitoring by a HR monitoring device or one-lead ECG recordings [7,10,11].

Arriving at the scene, the EP requires the history of the event, a read-out of the vital signs and symptoms, and the measured parameters. Communication of these data to the ED staff was examined especially for emergency service personnel (ambulance staff, nurses, EPs). There was a considerable loss of orally transmitted information by transferring the patient to the ED [12,13].

The possibility of checking these records retrospectively, is not only useful to review data during the period between the GP's and the EP's arrival. Data can also be reproduced at a later stage, e.g. during transport of the patient or during stay at the ED. The information of AEDs for instance, used in out-of-hospital cardiac arrest by bystanders, is important to examine the onset and evolution of the cardiac rhythms and bystander basic life support [14]. Also, all information, recorded by a GP before the arrival of the EP, is crucial to support diagnosis, treatment and prognosis.

After an extensive literature review, I did not find a single paper on the use of portable monitoring devices by GPs in out-of-hospital emergencies. There are many devices on the market capable of measuring more than one parameter. Unfortunately, most of them are too large and heavy, and do not record all parameters, are unable to transmit results to another device, or do not contain a reproducible memory.

I found a monitoring device, called PICO^{TM}, which is portable, fits in a doctor's bag, and immediately shows all parameters and curves on the display, similar to the EDs' monitors [15]. The data on this device can also be transferred on-site to a computer in which retrospective review of the parameters is possible. All data are saved on both devices. Although this device is not yet commercialised, the future aim is to transfer the data to any device such as a tablet or a smartphone and by all possible means of communication to the prehospital or ED staff.

We aim to investigate if

1. the use of the PICO^{TM} monitoring device could improve GPs' decisions to refer to hospital or not in urgent cases;
2. there is a difference between the diagnosis with and without the use of the monitoring device using the final diagnosis by the electronic health record of the own GP of the patient;
3. the call to send a GP for an emergency contained sufficient information for the OHGPS phone operator to take an appropriate decision:
4. the build-in alarms help the GP during his intervention;
5. the PICO^{TM} is easy to use during an emergency;
6. the use of the device makes them feel more confident in transmitting the information to the MET.

METHOD

Study Design

During this prospective randomized controlled trial, we will include all patients contacting the OHGPS via 112 or 1733 over the phone who are subsequently visited by physicians from OHGPS in Belgium. If recruitment is slower than anticipated, a second OHGPS will be recruited.

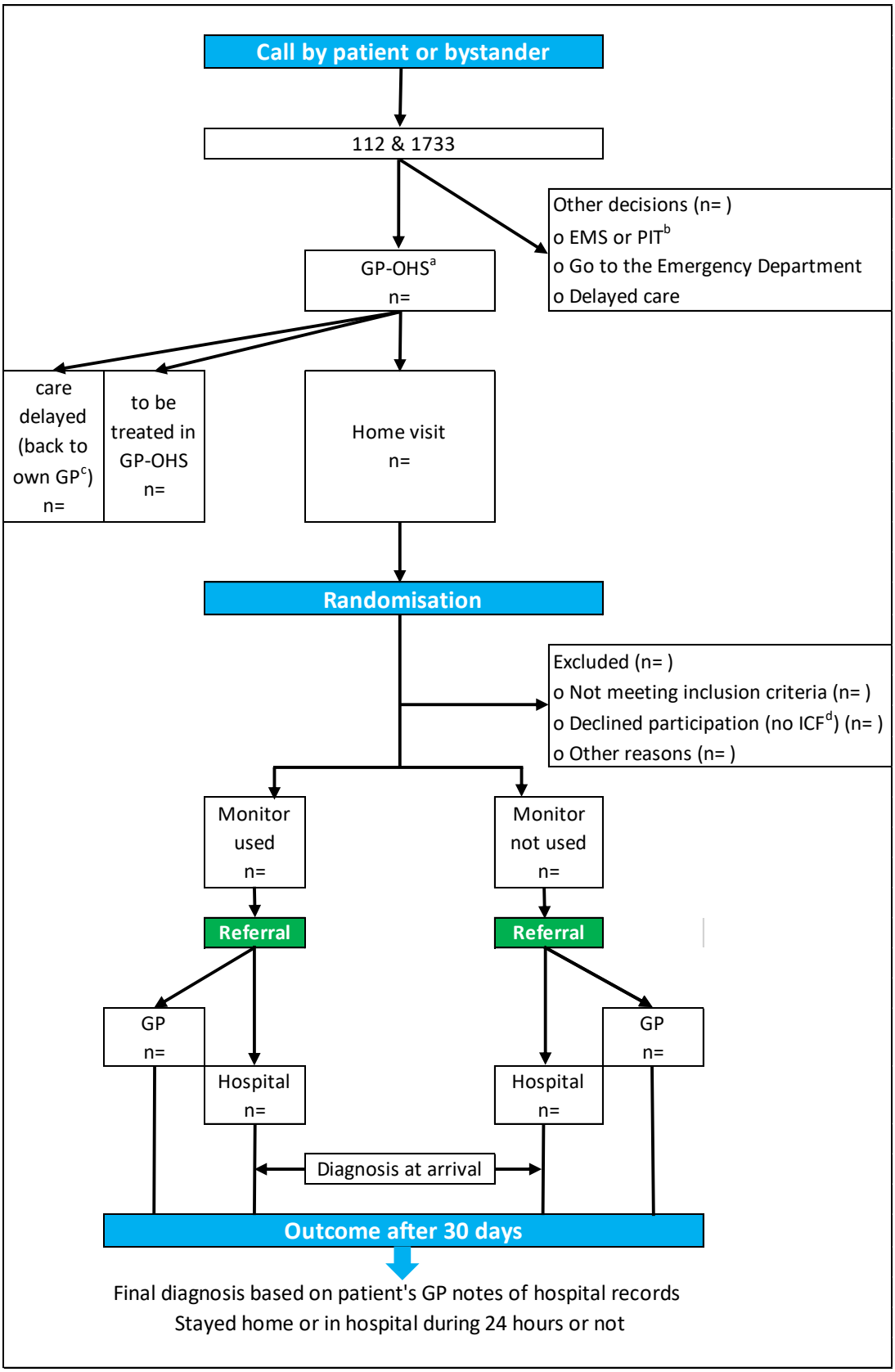
Whenever a patient requires medical help, his family or a bystander can call the 112 emergency number or, if a GP is needed, the 1733 number (Figure 1).

The urgent calls received by the OHGPS phone operator are transferred to the GP on duty. For the other calls, the patient is invited to go to the OHGPS. For home visits, GPs have a dedicated car with a chauffeur at their disposal, to avoid parking problems and to have additional support available (Figure 1).

For each home visit, GPs on duty register all visits, urgent and not urgent, as they usual do. Because they have to write a report to the patient's GP, presenting complaint(s) and diagnosis are recorded for every home visit.

Before the study, all GPs and chauffeurs are informed about the study design and the detailed procedures, and have to sign the informed consent form (ICF) respectively for GPs and chauffeurs. The main researcher developed an extensive training video showing how to use the PICO^{TM} monitor. All GPs and chauffeurs of the OHGPS have access to this video at any time and will receive a written manual.

Each patient seen at home is considered as having requested an urgent visit and, consequently, is eligible to enter the study. Before entering the residence, each patient will be allocated to one of two arms, according to the results of the randomisation process [16] (see the procedure in the statistics section). The first arm is the intervention arm where the monitoring device (figure 2) is used, additional to usual care, and the second arm is usual care only, without the use of the monitoring device.



[a] GP: general practitioner; [b] EMS or PIT: Emergency Medical Service or Primary Intervention Team

[c] GP-OHS: general practitioners' out of hours service; [d] ICF: informed consent form.

Figure 1: flowchart of calls arriving at the emergency dispatch centre in the region of Leuven, Belgium

To be able to include the patient, the GP needs to obtain an ICF from the patient or his legal representative or when the requirements of the WMA Declaration of Helsinki are fulfilled (articles 29 and 30) [17]. The reasons for including a patient if no IC can be obtained and if there is no legal representative present, are: a comatose patient, patients with stroke, patients unable to speak, patients in critical situations in which the GP does not have sufficient time to obtain the informed consent. E.g. acute HF with acute pulmonary oedema, patients with hallucinations or confusion from any kind of origin, patients who give oral informed consent but afterwards suffer of cardiac arrest (resulting in the GP to initiate CPR). In all other cases, when taking an informed consent is deemed not feasible, the reason will be recorded on the patient's ICF.

Once the patient can be included, the GP performs his clinical tasks (examination). The chauffeur applies the PICO^{TM} device (figure 2) according to the randomisation process. He checks if all parameters and curves are correctly recorded. The GP can follow the evolution of these measurements and both the GP and chauffeur will be alarmed if the device records any abnormal parameter result in a patient.

Immediately after the home visit, the GP completes an 'intervention form' as usual, containing the reason of the call, the probable diagnosis, decision and treatment. Additionally, the self-recorded parameters, the use of the monitoring device (yes or no), the level of urgency, the confirmation that an informed consent is obtained, the user-friendliness of the device, its utility and if the use had any influence on their intervention and/or decision, will be recorded. How the communication with the healthcare professionals went will also be recorded.

The objective is also to retrieve the diagnosis of each case 30 days after the intervention, from the patients' regular GP's health record and, if the patient was admitted, from hospital.

The monitoring device

The PICO^{TM} is a stand-alone patient monitor displaying 0-2 curves and/or 0-6 measured or calculated parameters which can be displayed simultaneously while the monitoring function is working. The device can be operated by using its touchscreen and buttons and has a 3-level alarm system that indicates whenever a parameter is out of the set limits [18].

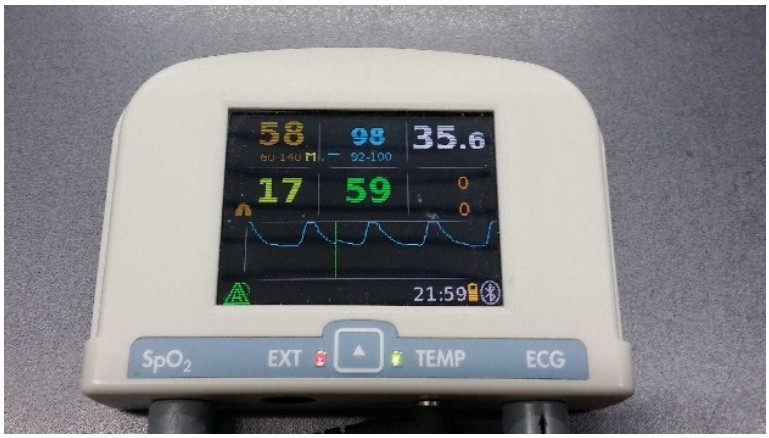


Figure 2: The PICO^{TM} monitoring device. From left to right and from top to bottom: HR, SpO_2, temperature, RR, pulse rate, the blood pressure parameters and one of the vital signs curves, in this case the SpO_2 curve.

The basic functions of the monitor (ECG, respiration, temperature and SpO_2) are preconfigured. However, external measuring modules can be connected. Respiration is measured by measuring impedance (from the ECG electrodes), SpO_2 and pulse rate through a pulse-oximeter and temperature with one channel measurement. The 3-channel ECG displays HR and arrhythmia analysis. Systolic and diastolic parameters of blood pressure can be entered different times manually. With the Bluetooth network connectivity all data can be transferred to a PC or tablet on which a special developed software shows the parameters and curves as on an ED monitoring screen [18].

Inclusion criteria

Registration of the numbers of calls at the 112-1733 dispatch centre and the results of the triage decisions will be done. From the calls sent to the OHGPS dispatch centre I will investigate how many are triaged to either delay of care by referring patients back to their regular GP, invitation to attend the GP's out of hours centre or sending out a GP for an urgent home visit.

All GPs on duty and chauffeurs of the OHGPS in Belgium, present during the study period are recruited after signing an ICF. GPs' age, gender and years of practice will be recorded. (Table 1).

All patients 18 years of age and older, for whom a home visit is requested, seen by a participating GP will be included if the informed consent form is signed either by the patient or by the legal representative, either onsite or at a later time.

Table 1: Demographics of GPs and of patients, distribution of patients (total number of patients seen during study period: N=…)

		GPs		PATIENTS									
				Total number of home visits*		Excluded (N=)				Included urgent visits (N=)			
						No ICF		Other reasons**		PICO™ not used		PICO™ used	
		N=	%	N=	%	n=	%			n=	%	n=	%
Gender	M												
	F												
Age	Mean												
	Min												
	Max												
Practice	2 or more GPs												
	Solo												
	GP in training												
Experience	> 25 y												
	6-25 y												
	0-5 y												

Total number of patients managed at OHGPS ***			
	N=	M (n=) (%)	F (n=) (%)
Care provided at the OHGPS			
Care provided during home visits by OHGPS	d	d D	d d

* Total number: total number of patients for whom a home visit was requested during the registration period.

** Other reasons: when the GP on-call deems the intervention as not urgent, ICF withdrawn after previous acceptance, ….

*** Distribution of patients: number of patients cared for onsite in the OHGPS and number of patients for whom a home visit is requested.

Exclusion criteria

Patients younger than 18 years of age, not seen during home visits, failed to provide informed consent, with an acute trauma but not in a possible life-threatening situation (e.g. a broken bone), found lying on the street or seen after the intervention of an ambulance, a PIT or a MET (because in such situation monitoring devices are already on scene before arrival of a GP).

Reasons for exclusion will be recorded (not meeting inclusion criteria, refusing to participate, other reasons): these patients will not be included in the study.

Statistics

Randomisation

The cases are randomly assigned to two arms on a 1:1 ratio (via random number generator on "http://www.radom.org" [16]): 1 group with and 1 group without the use of the monitoring device PICO™. Randomization will be stratified at the OHGPS level and by GP's intervention vehicle and will be randomised in blocks of 6.

Sample size

The OHGPS is open on weekends, from Friday 19:00 h until Monday 08:00 h, and the service responds to an average of 54 calls for urgent home visits per week-end. Based on prevalence of emergency

diagnoses in the Intego data [19], I calculated that 10% of the calls are very urgent and 25% require an urgent decision but are not always followed by a hospitalisation. The presumption is that GPs generally refer 21% of the patients inappropriately to hospital or to patient's own GP. To achieve a minimal clinically significant difference of 11% more patients receiving an appropriate decision regarding referral to hospital or not in the intervention group compared to the control group, one will need 866 patients, 433 patients in each arm.

To yield minimally 866 included patients during urgent home visits, the estimation that the study will last for minimum 6 months is based on the consideration that an average of 25% of patients will not provide informed consent.

Data recorded

The aim is to record

- the number of calls at the 112 dispatch centre by means of the 112 or 1733 dial number and the 112's decision.
- the number of calls dispatched from 112 to the OHGPS phone operator.
- the decision of the OHGPS phone operator.
- all data on the intervention form for both study arms, for each patient, who gave IC. These data consist of those filled in by the GP on-call immediately after the intervention (Table 2)
    - first (when deciding on referral) and final (when completing the intervention form) diagnostic hypothesis;
    - referral to hospital or not;
    - parameters and curves inspected and results;
    - if any alarm was given and noticed;
    - the impact of the device parameters on the decision;
    - if the device brought new elements;
    - the feeling of the GP about the improvement or not by the device in communication with the healthcare professional;
    - which parameters helped the communication and if they were showed of viewed by the EP.
- After 30 days
    - the information provided by the patient's own regular GP, regarding the patient's outcome;
    - the information concerning the diagnosis at arrival at the ED and, if available, the outcome of the patient until day 30 of the hospital admission.

Analysis

I will compare the amount of (verified or experienced) emergencies with the non-urgent home visits, the number of patients correctly referred to hospital or not. The difference in proportions in both groups will be tested by the Z-test. I will also test for the difference in proportions in the groups using the monitoring device and the usual care group, with the z-statistic for two-sample test of proportions reporting the z-test statistic and the associated *p*-values. All *p*-values smaller than 0.05 will be considered statistically significant. The statistical analyses will be performed with R software version 3.5.1 [20].

The definition of an incorrect referral is stated as follows:

- When a patient is referred to hospital and released within 12 hours. However, if the referral is made only for a diagnostic test, e.g. an X-Ray, an ECG, a blood test, advice of a consultant ., and no hospitalisation followed, it is considered as a correct referral.
- If a patient is referred to hospital only for a diagnostic test (e.g. X-Ray) and no hospitalisation is requested, but an in-hospital decision is made to hospitalise the patient.
- If a patient is referred to his own GP but needs a hospitalisation within 48 hours.

The principal investigator (WSR) will code the recorded diagnoses of the home visits according the International Classification of Primary Care (ICPC) [21]. He will compare the diagnoses made during home visits with the overall amount of diagnosis in the Intego registry of diseases in the Flemish population of Belgium [19] to assess generalisability. He will compare for each patient and for the whole study the reason(s) for encounter with the first and final diagnostic hypothesis of the GP and the number of patients referred to an hospital, correctly and incorrectly, and by which mode of transportation they are transported to hospital (Appendix).

In the intervention arm the aim is to know which parameters and curves are observed and, if possible, are needed for GPs. The use of the monitoring device will also be checked, as well as the parameters and curves the GPs mentioned to have used, and the alarms recorded by the GP have had an influence on management of the patient. The comparison of the mentioned alarms to the ones recorded in the monitoring device will also be investigated.

I will study whether the device is user-friendly, if it has an influence on communication and, consequently, to find out which items were important with regards to specific pathologies.

All written comments will be coded by two independent researchers (WR and JV) and, after agreement, conclusions will be stipulated.

The quantitative data will be analysed with MedCalc [22] and R software version 3.5.1 [20] for differences between both arms in proportions of patients correctly referred to hospital or not. For the qualitative data, the answers using the framework method [23] will be coded and conclusions of both investigators compared using kappa statistics.

For missing data, I will report the number of missing values for each variable of interest, describe the reasons for missing data and indicate how many individuals are excluded. I will clarify whether there were important differences between individuals with complete and incomplete data. If appropriate and if the assumption that missing data was at random has been met, multiple imputation based will be attempted [24,25].

The intention is to analyse the study with the Intention-To-Treat (ITT) principle, including all patients who gave their informed consent, ignoring what happened to the patient afterwards.

Expected duration of trial

The study will last for six months, depending on the number of recruited patients with a minimum of 866 cases where an ICF is obtained or when article 29 and 30 of the WMA Declaration of Helsinki is applicable.

Quality assurance

The device, InnoCare PICO^{TM}, Type IMH-8M is a portable colour patient monitor and developed, manufactured and distributed by Innomed Medical Inc., *Medical Developing and Manufacturing Inc.,* Hungary-1146 Budapest, Szabó József u. 12, Tel: +36-1 460-9200, Fax: +36-1 460-9222, http://www.innomed.hu, and labelled CE 0120.

Ethics and regulatory approvals

The study was approved by the ethical committee of KU Leuven under the S-number S63046 on 2020, October 07.

DISCUSSION

Feasibility of the study

In order to be able to design the study, it was necessary to know whether sufficient acute cases could be included for this study. To do so, we first contacted the responsible persons and requested the number of urgent calls and home visits. Based on their figures about the number of home visits, it seems feasible to start the study. As explained, both emergency numbers arrive at the central dispatch. Consequently it is possible that less urgent cases will reach the OHGPS because the 112 dispatcher

assumes that a specific call coming from 1733 needs immediate intervention by the MET, PIT or ambulance. Future studies should examine the distribution of calls and compare the decision to the outcome.

Introducing the study and the monitoring device

GPs regularly see urgent cases at home during their out-of-hours service and carry their usual doctor's bag with them. For this study, however, they will be burdened with extra tasks, namely the introduction of the monitoring device. Therefore, it is needed to clarify the following points: how to introduce the monitoring device into the routine of the GPs, how can the use of the PICO^{TM} be explained to the GPs and chauffeurs, who will apply it onsite, what are the requirements to be able to apply this device?

To introduce the study and the monitor, we need an agreement of the people in charge of the OHGPS. Two meetings will be organised, one for the GPs and one for the chauffeurs, to explain the design of the study and how the process will be developed. These meetings have not taken place yet due to the current pandemic (see below).

To explain how to use and apply the PICO^{TM}, a written manual and an extensive video have already been prepared. Each participant will receive a written copy and access to the training video at all time.

Since in case of urgency GPs must be able to focus on the patient, we decided that the chauffeur would accompany the GP to the patient and connect the device if asked to do so according to the randomization process. One of the reasons is that the turn-over of the chauffeurs is lower than of the GPs on call, which means that the risk of errors due to incorrect application or protocol violations will also be lower.

Urgent home visits

Each time a patient asks a doctor for a home visit during out-of-hours periods, it is considered as an urgent call. For a non-urgent problem, the patient is considered to be able to visit the OHGPS, where a physician can be consulted. Therefore, it was considered feasible to perform randomisation before the patient was seen.

Randomisation

For this randomised control trial, the number of cases needed is first calculated. Each case is allocated to the result of the randomisation. The monitoring device will be installed accordingly. It was decided to stratify at the OHGPS level and by the intervention vehicle. For each vehicle, the block randomisation will be applied in blocks of six. Each intervention form will be used according to the assigned rank number for which an envelope with the result of the randomization is provided. Block randomisation

was chosen because sometimes two vehicles and GPs are on the road at the same time and home visits can therefore be executed simultaneously.

Consequently, at the start and certainly before the GP leaves the vehicle, the randomisation envelope will be opened to know if for that specific home visit the monitoring device will be used. If the decision is to apply the monitoring device, the chauffeur has to accompany the GP. In the other situation, he will not and the GP will provide care as per usual.

In the intervention arm, the monitoring device will be applied, with one pulse oximeter device on a finger and five electrodes on the bare chest of the patient for an ECG. If needed, the GP can also apply the thermometer. When another investigation is done simultaneously, e.g. a full ECG record by another device, this will be considered as usual care and mentioned in the intervention form.

Informed consent form and patient's agreement

At each home visit an informed consent must be obtained, as required by Belgian law and at the request of the ethics committee. The patient is given a short explanation orally, after which the patient can give his oral consent, which must be noted on the intervention form. The ICF, drawn up in duplicate, must be signed by the patient or his legal representative and by the GP.

In a very urgent situation, obtaining informed consent will be difficult, such as with a very seriously ill patient or if he or she is alone. There is then either hardly time to provide much explanation or the patient can hardly or no longer understand. The explanation should be very short: the GP should ask the patient if he agrees that the home visit may be part of a study and that it will not affect his health status in any way. If the device has to be installed, it will also be stated that it is only installed non-invasively.

In order not to lose important information, it is decided that in these cases, after the intervention, one should try to contact the patient or his legal representative. If this is not possible, the obtained data must be excluded from the study. Although, based on the WMA declaration of Helsinki, the data of some patients can still be used. This is also stated in the ICF. The declaration states that research involving subjects who are physically or mentally incapable of giving consent, for example, unconscious patients, may be done only if the physical or mental condition that prevents giving informed consent is a necessary characteristic of the research population. If no legally authorized representative is available and if the research cannot be delayed, the study may proceed without informed consent provided that the specific reasons for involving subjects with a condition that renders them unable to give informed consent have been stated in the research protocol (see study design) and the study has been approved by a research ethics committee (see below).

It is up to the researchers to check whether these conditions have been met and whether the GP has written down on the intervention form the reason for not obtaining the informed consent and the diagnosis.

Alarms of the monitoring device

The alarms are produced by the device when a wire is not registering or is disconnected, when the battery is low, when apnoea or asystole is present, or when the value is out of the set limits for each parameter. Therefore, alarms will be enabled on each device and the upper and lower limits will be set on each device. I will use the device's pre-installed lower limits: for SpO2 ≤92%, for respiration rate (RR) at ≤10 respirations per minute and the upper limits for temperature at ≥39°C and for HR at ≥ 120 beats per minute (bpm). I will change the automatically set lower limits for pulse rate and HR at ≤50 bpm instead of 30 bpm and the upper limit for RR to ≥30 respirations per minute.

Referral

The data produced by the device could help the GP to follow the evolution of the disease and to establish his tentative diagnosis. Deciding about the treatment and referral of the patient to hospital or to their own GP, is the responsibility of the GP and is based on his usual approach of the situation.

It was needed to decide what a correct referral is. A referral to the patient's own GP is considered incorrect if the patient cannot be treated at home up to 48 hours after the initial urgent visit and has to be admitted to hospital. It is however considered as correct if the patient needs to be hospitalised for another reason than the reason of the home visit. In exceptional cases, the patient could request a new urgent visit during the same out-of-hours period. The visiting GP will include the patient if the informed consent is obtained and follow the study procedure, but will record that the patient was seen less than 48 hours before. The first home visit referral is consequently considered as incorrect. It is also possible that a patient is transported by ambulance or MET within 48 hours of the GP on-call visit: the referral will then be considered as incorrect if the patient was initially sent home, based on the records obtained from the patient's own regular GP, 30 days after the first intervention.

For hospitalised patient the discussion about correct referrals leads to important decisions. The threshold is set at 12 hours. When a patient is referred to hospital for admission and he stays more than 12 hours in hospital (at the ED), it is considered a correct referral. A correct referral is when the patient is referred only for an investigation, e.g. a X-Ray or an ECG or a blood test, and was not hospitalised. If the referral for an investigation leads to admission to hospital, it is considered as an incorrect referral, as well as if a hospitalisation is requested and the patient leaves the hospital within 12 hours.

Parameters and communication

I currently could not find literature concerning the accuracy of the communication between GPs and EPs. However, it is described in the literature that the communication in-between emergency professionals at any level was not optimal and could certainly be improved [12]. They tend to focus on diagnosis and give incomplete information on parameters or signs and symptoms [13,26]. In this trial, the aim is also to assess whether the GPs' communication with the EPs is better when the monitor is used than when it is not used. Moreover, the objective is also to know which of the parameters is used as an additional argument in the communication, either orally, either by showing the parameter(s) on the device, or by recording the parameter(s) in the referral letter.

Comments of the GPs on-call

On the intervention form, GPs are asked to record elements regarding communication, user-friendliness of the device and general comments. All answers will be coded by two investigators separately and, in case of disagreement, after agreement between both or after consulting a third person.

Based on the results, general conclusions can be drawn for improvement of the device and for future research.

Outcome after 30 days

A letter will be sent to the regular GPs of the included patients 30 days after the GP-on-call intervention, to know if the patients stayed at home more than 48 hours and what the evolution was until day 30: cured, relapse, needed hospitalisation after more than 48 hours for the same reason or not, patient was not seen again or was not a patient of the practice. I also will check whether the GP received a discharge letter of the hospitalised patient. That information aims to evaluate the correct or incorrect nature of the referral by the visiting GP on-call.

For hospitalised patients, the diagnosis made in the ED and the follow-up until day 30 will be investigated. This information will be gathered by one of the co-authors.

All information will be reviewed by minimum 2 researchers in order to reach agreement.

Duration of the study

It is possible that the duration of the study could last for more than 6 months due to physical and technical constraints caused by the COVID-19 pandemic. GPs suffer from a high workload during this period and they must also take the necessary measures to stop the spread of the sars-CoV-2. Introducing additional burden by this monitoring device is therefore not possible during this pandemic. Moreover, GPs will not be inclined to accept extra work caused by the requirements on using devices

during the pandemic. The latter is mandatory after each intervention and the limited number of available devices can cause a temporary interruption of patient enrolment. Furthermore, it is possible that more patients will be reluctant to sign the ICF during this pandemic.

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Appendix: Analysis of the calls, according to each patient included (Patient 1 until patient 866 = patient x+n): parameters, curves and questions on the intervention form.

		Patient 1	Patient 2	Patient 3	Patient x+…n
Patient	Code				
	Age				
	Gender (M=1, F=0)				
Reason for encounter	ICPC*				
First working hypothesis	ICPC				
Final diagnosis	ICPC				
Patient is hospitalised	(Yes=1)				
	with EMS$				
	with ambulance				
	own resources				
Use of PICO™	(Yes=1)				
	why not?				
Parameters used	SpO_2*				
	Pulse rate				
	Heart rate				
	Respiration rate				
	Temperature				
	BP* mentioned in device				
Curves controled	SpO_2				
	Respiration				
	ECG lead I				
	ECG lead II				
	ECG lead V				
Alarm given	(Yes=1)				
	SpO_2				
	pulse rate				
	heart rate				
	respiration rate				
Did PICO™ influence approach	(Yes=1)				
	to increase urgency				
	to lower urgency				
PICO™ brought new elements	(Yes=1)				
	was important (yes=1)				
Communication to MET	was better (yes=1)				
	no influence (yes=1)				
	was worse (yes=1)				
Parameters used in communication**	showed (yes=1) or orally				
	in referral letter				
Which parameters were used?	SpO_2				
	Pulse rate				
	Heart rate				
	Respiration rate				
	Temperature				
	Curves				
	ECG				
Userfriendliness	(1-10)				
	Comments				
General comments					

* ICPC: international classification of primary care; MET: medical emergency team; SpO_2: peripheric oxygen saturation; BP: blood pressure; ECG: Electrocardiogram

** Parameters used in communication can be transmitted by showing them (e.g. on the PICO™), or only by oral communication. Parameters can also be communicated in the referral letter.