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Improving transitional patient safety: research protocol of the Transitional Incident Prevention Programme

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Abstract

Introduction: Patient transitions between primary and hospital care include referral, discharge, and simultaneous care by the outpatient clinic and the general practitioner (GP). Research on referrals and discharge shows that safety incidents in these transitions are common. We developed the multifaceted Transitional Incident Prevention Programme (TIPP), which aims to improve transitional patient safety preventing future incidents. With this study, we aim to evaluate the effectiveness of the TIPP programme on transitional patient safety, and to evaluate its implementation and the acceptance in GP-practices and hospitals.

Methods: The TIPP intervention study is a controlled before and after study combined with qualitative methods. The study will be conducted in both rural and urban settings including three hospitals, together with referring primary care practices. The TIPP intervention is aimed at three aspects of transitional safety:
1) Healthcare process, 2) Transitional patient safety culture, and 3) Patient participation. Together with the participating hospital departments, GPs and patients, we will develop a tailored improvement programme, taking into account the different context of each setting.

Discussion: The purpose of this protocol paper is to present and discuss the research design and methodology of the TIPP intervention.

Trial registration: Dutch trial register NTR4810

Keywords: Patient safety, Transitional care, Transitions of care, Handoff of care, Continuity of care, Discharge, Referral, Outpatient, Hospital, General practice, Quality improvement

Background

Internationally, there is an increasing shift from secondary to primary care in order to reduce healthcare costs simultaneously with sustained quality and safety of care [1, 2]. This restructures care by creating healthcare chains that connect current organisations along similar patient groups, in which the general practitioner (GP) has a coordinating role [3, 4].

In these healthcare chains patients transfer from primary care to hospital care for diagnostics, treatment, and monitoring to receive adequate care at the right healthcare level. The increase of both collaborative care between different care levels as well as the number of patient transitioning enlarges the challenge of securing safe continuity of care, which in this study is summarised in the concept of 'transitional patient safety'.

Patient risks do not present homogeneously within the different care levels, for primary and hospital care differ in patient presentation, epidemiology of diseases and obviously also in organisation of healthcare [5]. Nor do these organisations share a common view on the concept of patient safety. These differences result in errors when patients pass the boundaries [4].

Indeed, research on patient transitions between primary and hospital care, e.g. discharge, referral, and

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simultaneous care at both levels, revealed many patient safety incidents. Numbers on incidents vary between 20 % [6] and 50 % [7] of discharged patients, depending on design of the study, definition and patient group. The incidents' consequences ranged from minor harm to disability and death and half were supposedly preventable. At referral, GPs often fail to communicate relevant patient information or the reasons for the referral to the specialist or patients are referred inappropriately according to the specialist [8]. Martinussen et al. showed that specialists considered only 15.6 % of the referral letters to be "usually good" [9].

To improve transitional patient safety, it is vital that healthcare professionals in primary and secondary care understand each other's working methods, and practice good communication and openness [10]. Many emphasize the need for a system-based approach in healthcare in which the patient has a central role [11, 12]. A system-based approach is defined as: the demonstration of "an awareness of and responsiveness to the larger context and system of healthcare and the ability to effectively call on system resources to provide care that is of optimal value." [13]

This system-based approach would facilitate physicians to move competently within the larger systems of care providing interdisciplinary, coordinated, and safe care [11], the main focus in this approach being the patient [3, 14]. The healthcare professional should learn to read the medical case stories from a patient point of view. This awareness may reduce adverse events, and help doctors to recognise the complete patient journey through the healthcare chain [15].

In such system, patients themselves also should be aware of their health status and their journey through the healthcare chain [16]. Indeed, they are the only constant in the whole process of the transition from general practice to hospital and vice versa.

Many tools aiming to improve the transition in referral or discharge have been developed and implemented [6, 16–20], such as regular meetings between GPs and specialists, case managers, the patient record (either patients carrying their own patient health record or accessible digital medical records for patients provided by the hospital), discharge guidelines, and guidelines for referral and discharge letters. However, only few tools have been systematically studied on their effect [21]. Also, these tools have been studied separately whilst a comprehensive intervention targeting the healthcare process, culture and patient aspects simultaneously seems more appropriate for improving transitional patient safety.

We developed a multi-faceted programme (the Transitional Incident Prevention Programme; TIPP) to improve transitional patient safety and prevent future incidents. With this study, we aim to evaluate the effectiveness of the TIPP programme on transitional patient safety, and to evaluate its implementation and the acceptance in GP-practices and hospitals.

Methods

Study design and hypotheses

The TIPP intervention study is a controlled before-after study which will be conducted in two settings. We will use a mixed method approach to measure and explain the effectiveness of TIPP, combining quantitative and qualitative research methods. The effectiveness of TIPP will primarily be evaluated overall, but also within the two settings separately. Figure 1 shows a flow diagram of the study design.

We include a convenience sample of two voluntary participating health regions in our study. Both regions include at least one hospital and multiple general practices. The two regions contrast in setting, i.e. rural vs. urban, which will provide sufficient heterogeneity to assess the influence of contextual factors on the effect of TIPP.

We hypothesize that: (i) Implementing TIPP will reduce unplanned emergency room (ER) visits, rehospitalisation and inappropriate referrals (ii) Implementing TIPP improves the transitional patient safety culture, (iii) Implementing TIPP reduces healthcare costs due to preventing ER visits, rehospitalisation and inappropriate referrals.

In addition, we will conduct a process evaluation, assessing acceptability, appropriateness, and feasibility of the intervention in each setting, related to the differences in contextual factors that influence adoption, fidelity, and penetration of TIPP [22].

Study settings

Rural setting

The first rural region consists of a regional hospital (Röpcke-Zweers, 197 beds), together with 18 referring primary care practices in the same region. Together these healthcare professionals treat the majority of patients in this area. The estimated number of patients in this area is 68000. We will focus on healthcare paths with high turnovers, in which many transitions are expected. In this rural area, we will limit our intervention to medical disciplines internal medicine (including gastroenterology) and cardiology.

Urban setting

The second setting consists of two hospitals, a University Hospital (UMC Utrecht, 1042 beds), which provides both nation-wide and regional care and a smaller city hospital (Diakonessenhuis, 480 beds). Together they provide hospital healthcare for the patients in the Utrecht area. In addition, we have selected 44 referring

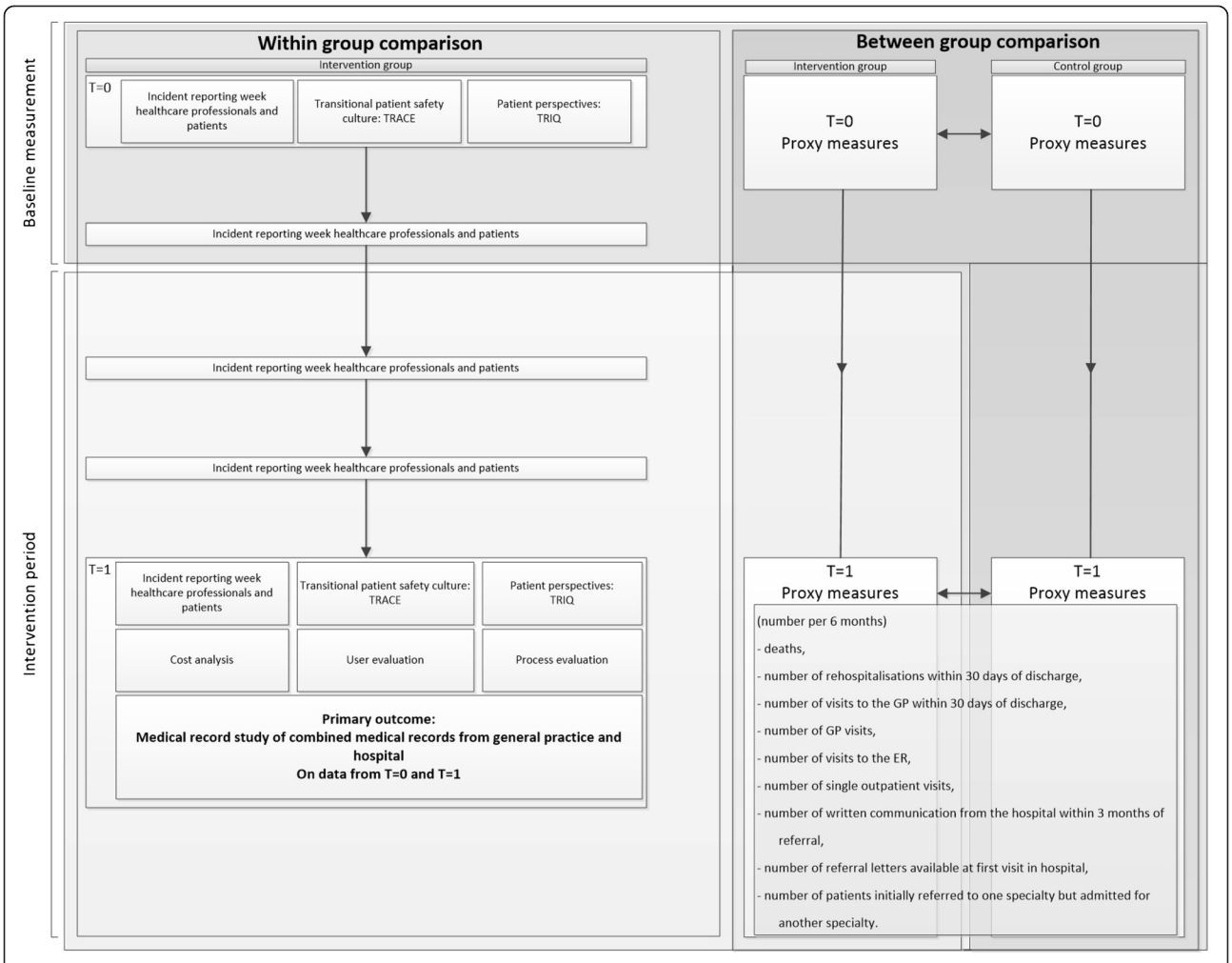

Fig. 1 Flow diagram of the design of the TIPP intervention study. The TIPP study is a controlled before-after study. This figure shows the outcome measures of the between and within group comparison in time. The time period between T = 0 and T = 1 is approximately 18 months

primary care practices, working in two collaboration groups in the Utrecht area. The estimated number of patients in this area is 194000. In this urban area, we will limit our intervention to the cluster of 'medical disciplines' gastroenterology and cardiology.

Control group

The control group consists of the non-participating departments in the hospitals in the Utrecht region, and the non-participating general practices in the larger Utrecht area. These departments and practices continue to work as usual.

Patient selection

We will include patients in usual care who are at risk for a transitional incident. These patients have experienced a transition from GP to hospital or vice versa: they have either been referred to or discharged from hospital, or have visited the outpatient clinic at the time of the study. It is a dynamic population.

Intervention

TIPP is a multi-faceted intervention containing several components aimed at different aspects of transitional safety, developed in an earlier phase of the project using the Intervention Mapping approach [23]. With extensive literature search and qualitative methods we assessed both general transitional safety problems, as well as the major setting-specific transitional problems.

We identified three important aspects of transitional safety:

1) The healthcare process
2) Transitional patient safety culture
3) Active patient participation

In the TIPP programme each aspect will be targeted by either general or setting specific intervention components. The components can be tailored to the specific wishes of each setting because implementation of a complex intervention largely depends on context [24, 25].

Healthcare process

The intervention component aiming at the healthcare process consists of a renowned risk assessment tool such as a prospective risk analysis of a major problem in their setting or the systematic report and analysis of transitional incidents. These tools will identify the most common processes that fail during transition of care for each participating hospital department together with the referring GPs [26, 27]. In addition, we will provide existing tools to improve these processes. The participants themselves are responsible for designing and executing their own improvement plans. We will include and facilitate both (i) already existing plans that touch on and influence transitional care (e.g. an initiative to improve medication reconciliation) and (ii) initiatives of healthcare organisations which originated from the TIPP diagnosis of transitional care.

Transitional patient safety culture

We will organise a transitional safety workshop for professionals. In this workshop we will provide information about transitional safety, but especially focus on creating a shared vision of communication, collaboration and responsibility in transitional care. Also, introducing the GPs and specialists to each other is an intervention in itself [28, 29]. Preliminary results of a qualitative study suggest this will lower the threshold for spontaneous feedback between professionals, in order to facilitate approaching the colleague to whom the patient is transferred for discussing medical policy or problems. Furthermore, mutually reporting and analysing transitional incidents together are culture interventions themselves [27].

Patient participation

From the start, patients are involved in the TIPP project (i) through participation of the Dutch Federation of Patients and Consumer Organisations in the Netherlands (NPCF) in the advisory board of the project, (ii) participation of trained patients in the local project groups that determine the intervention components, together with representatives of the participating hospital departments and GPs, and (iii) through patient interviews with patients that have experienced a transitional incident preceding the trial.

We used the information gathered from these patients to create a tool for patient empowerment: a patient info card. The patient info card provides information to address major safety items in transitional care using cartoons and short easy understandable language [30]. During the intervention period, the hospitals and GPs will be requested to supply this card to their patients.

Many other patient tools have already been created to minimize transitional risks (e.g. a patient record: either patients carrying their own patient health record or accessible digital medical records for patients provided by the hospital, medication lists, patient access to medical files [31, 32]). The local project groups, consisting of patients involved in regional and national patient unions, staff from our participating hospital departments and affiliated GPs, will decide whether they will use one or more of these tools, and if so, which one. The patients in our local project groups are "professional" patients recruited by patient platforms for helping with quality improvement.

Table 1 shows examples of improvement plans for each of the three important aspect of transitional safety.

Outcomes and measurements

Primary outcomes of between group comparisons

We will use the following proxy measures to assess the effectiveness of the intervention: death, number of rehospitalisations within 30 days of discharge, number of visits to the GP within 30 days of discharge, number of GP visits, number of visits to the ER, number of single outpatient visits, number of written communication from the hospital within 3 months of referral, number of referral letters available at first visit in hospital, and number of patients initially referred to one specialty but admitted for another specialty. All proxy measures are measured in a six months' time period.

Within group comparison

Within the intervention group we aim to assess the effect of TIPP in more detail. Because we measure in more detail, we use more sources of data. Also, we use qualitative measurements to better understand the links between theory and empirical findings.

Study parameters for this within intervention group comparison are:

1) The proxy measures from the between group comparisons.
2) A composite endpoint of: serious adverse events (death, possibility of death or major permanent loss of function), unplanned visits to the ER, re-admission within 30 days, and non-appropriate referrals, all within a six months' time period. This composite endpoint will be extracted from a different data source from the proxy measures.

Table 1 Examples of intervention components for each of the three important aspect of transitional safety voiced by the TIPP participants

Health care process	Transitional patient safety culture	Patient empowerment
Transitional incident reporting committee: Providing a neutral place for feedback of incidents, will provide insight in system errors in transitional patient safety and fosters improvement of the healthcare process. Also, it improves transitional patient safety culture by stimulating feedback between GP and hospital and exchanging news.		**Patient info card:** providing information to patients to address major safety items in transitional care using cartoons and short easy understandable language
Safe email communication: providing a place to communicate short messages about specific patients. This does not replace the extensive communication (e.g. discharge letters), but offers a place to communicate important (but not urgent) messages about medical policy requests (e.g. control lab tests a week after discharge) or changes (e.g. medication changes after outpatient visit)	**Transitional patient safety culture workshop:** Introducing GP's and hospital professionals and providing information about transitional risks and safety, to create a shared vision on communication, collaboration and responsibility in transitional care. Introducing the professionals to each other will lower the threshold to communicate and provide feedback on specific patients.	**Medication passports:** providing patients with (empty) medication passports before the first outpatient appointment. A patient will be requested to fill in the passport according to the medication they use at that moment. There is also room for their medical background and allergies.
A prospective risk analysis (PRA) or Healthcare Failure Mode and Effect Analysis (HFMEA) of a regional problem in transitional care. E.g. an HFMEA on discharge of patients from the outpatient clinic to the GPs or hospital diagnostics requested by the GP (like gastroscopy or cardiac stress test) [26, 27].	**Regular (half-yearly) informal gatherings between professionals from GP and hospital:** personal acquaintance between professionals from GP and hospital will lower the threshold to communicate and provide feedback on specific patients.	**A patient health app:** providing a patient with a digital medication passport on their smartphone or tab to register their medication, medical background, and allergies and update the medication regularly (after every adjustment).

GP = general practitioner

3) Number, nature and harm of incidents collected through a combination of methods: professional- and patient-reported incidents and incidents found in a medical record review.
4) Transitional patient safety culture according to the healthcare workers, as measured by the TRAnsitional patient safety Culture Evaluation (TRACE) (see § Data collection; Transitional patient safety culture).
5) The costs of (avoided) visits to the ER, readmissions, non-appropriate referrals and incidents in a six months' time period compared to the direct costs of TIPP.
6) Patient perception of transitional patient safety, as measured by the Transitional Risk and Incident Questionnaire (TRIQ) (see § Data collection; Patient perceptions on transitional patient safety and incidents).

For the process evaluation we will qualitatively assess the following aspects:

1) Components of TIPP that were actually implemented and used in the healthcare chain (process evaluation)
2) Experiences of participants (user evaluation)

Measurements and instruments

Between group comparison

General Practitioners and hospital database; proxy measures for transitional care will be collected from the routine care data registries of the participating general practices and from the hospital database for each participating hospital departments.

Within group comparison

Patient and professional characteristics The patient characteristics collected are: gender, age, education level, co-morbidity and the number of types of medication used at this moment. The professional characteristics collected are: gender, age, function, and working experience (years).

Medical record review study At both T = 0 and T = 1, a trusted third party (TTP; an independent organisation) will select a random sample of patients equally spread over all participating hospital departments who were at risk of transitional incidents in the last 6 months. These patients will then be cross-referenced with the database of the GPs in our study group, and a random selection of patients will be pulled from these. Then, the TTP will link the GP and hospital files and anonymise them. Trained employees will screen the records by using triggers indicating potential transitional risks or incidents. Because no trigger tool exists for transitional safety problems, we are developing a transitional trigger tool. Medical records positive for at least one trigger will further be reviewed by a physician. They will be trained in recognising and evaluating transitional incidents. Patient characteristics (age, gender, comorbidity and total number of medicine used at this moment) and characteristics of incidents (type, harm, location) will be scored. According to the Eindhoven Classification Model, the type

of incidents will be scored as incidents in organisation, technology, human behaviour, or as patient related [33]. Harm and potential harm will be classified according to The National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) harm index [34], which is a 9-point scale from "none" to "death".

For our composite endpoint, data on serious adverse events, acute visits to the ER, re-admission within 30 days and non-appropriate referrals will be registered. To assess the inter-observer reliability of the doctors' review, a second doctor will review a random sample of records and the absolute agreement and intraclass correlation coefficient (ICC) for inter-observer agreement (absolute agreement, single measurement) will be calculated [35]

Incident reporting Approximately every 4 months, the professionals (the entire staff of the participating hospital departments and GP practices) and patients will be requested to report all transitional incidents for a week. Hospital personnel will report through the hospital incident reporting system, which will be slightly adjusted to fit transitional incidents. GPs will use a confidential digital reporting system that can be traced back to the reporting professional and patients can use either an anonymous paper or digital incident reporting form.

A team consisting of at least one independent specialist, one independent GP, and a researcher experienced in analysing incidents will judge incidents based on the characteristics of the incidents (type, harm, location) as mentioned in the medical record review study.

Patient perceptions on transitional patient safety and incidents Because no questionnaires existed for this purpose, we developed the Transitional Risk and Incidence Questionnaire (TRIQ) which was based on literature and qualitative research. The TRIQ is a questionnaire asking patients whether they have experienced risky situations and transitional incidents. In the development of the TRIQ, we used Reid et al's [36] framework for continuity of care (a related term, but broader than transitional care, for it also contains the continuity within one organisation). The framework consists of three dimensions: relational continuity, informal continuity and communicational continuity. The development of the TRIQ will be described elsewhere. During the TIPP trial, patients will be requested at T = 0 and T = 1 to fill in the TRIQ. Patients at risk for transitional incidents will be selected at the outpatient clinics. The patient can either fill in the questionnaire by him/herself or be assisted by a medical student.

Transitional patient safety culture Because no questionnaires existed for this purpose, we developed the TRAnsitional patient safety Culture Evaluation (TRACE) which was adjusted from two current patient safety culture questionnaires used in the hospital setting (Dutch version of the AHRQ Hospital Survey on Patient Safety Culture; HSOPS) [37] and in a general practice (SCOPE questionnaire, which is derived from the Dutch version of the HSOPS, SCOPE is a Dutch acronym for systematic culture inquiry on patient safety) [38]. The development of the TRACE will be described elsewhere. During the TIPP trial, professionals (all personnel with experience in transitional care from the participating hospital departments and general practices) will complete a patient safety culture questionnaire at T = 0 and T = 1.

Cost-analyses The costs of (avoided) visits to the ER, readmissions, non-appropriate referrals, and incidents, all within a 6 months' time period, will be compared to the direct costs of TIPP. The evaluation of the costs of (avoided) visits to ER, readmissions, referrals, contacts at the GP practice and incidents will be based on the most recent unit prices according to the reference prices for the Netherlands [39]. To estimate the costs of the TIPP intervention, all direct costs will be calculated. We will include all personnel costs in organising, executing and participating in the components of the intervention. We will exclude the developing costs of the intervention and all research-related costs to the TIPP research programme itself.

Qualitative data collection

Process evaluation We will assess the actual implementation of the TIPP intervention by measuring implementation outcomes: the adoption, fidelity, and penetration of TIPP [40]. These implementation outcomes will be collected from the participating hospital departments and GPs on a regular basis, using interviews, self-reporting and (participative) observations.

User evaluation We will collect information from the participating hospital departments and GPs on their experience with TIPP. We will use participant (including patients) observations, interviews and group interviews to assess acceptability, adoption, penetration and appropriateness of TIPP [41].

Context/Characteristics of healthcare facilities At the start of the study, the departments and GPs will be characterised by their context. In the participating GP practices we will observe and collect the following data: form of cooperation, yearly number of patients, patients' gender, ethnicity and mean age, full-time equivalent positions of GPs and other personnel, mean regional social economic status, number of competitive hospitals in the region. In the participating departments we will observe

and collect the following data: regional or university hospital; yearly number of patients; patients' gender, ethnicity and mean age; full-time equivalent positions of physicians and other personnel; mean regional social economic status, number of regional competitive hospitals, and number of referring general physicians. Also, key process indicators for implementation of patient safety interventions will be described using a framework based on the Model for Understanding Success in Quality (MUSIQ tool) [41].

Statistical analysis

Statistical power

The power calculation for the effect of TIPP is based on the primary outcome, as collected in the medical record study. The following assumptions are used: a reduction of frequency of transitional incidents from 17 % to 13 % (25 % reduction) with a power of 80 % and an alpha of 0.05. We expect an average of 2 transitions in each patient within half a year. The percentage of 17 % transitional incidents was based on literature study; we averaged the mean of re-hospitalizations and non-appropriate referrals in systematic reviews on discharge and referrals, which probably is a conservative estimation of the total of transitional incidents. We adjusted the sample size to the expected cluster effects [42]. This resulted in a sample size of 800 patients before and 800 patients after the intervention.

Patient- and setting characteristics will be analysed using descriptive statistics. They will also be used as possible determinants in the primary and secondary effects.

The difference in change in the primary outcome between intervention and control regions will be calculated using Poisson regression analysis, taking into account the clustering into departments and hospitals. Effects of implementation on transitional patient safety culture and patient perception will be calculated with multiple regression analysis, again taking into account the clustering into departments and hospitals. [35].

Cost-analysis will be analysed through subtraction of all direct costs of the intervention from the yield of the intervention (e.g. costs of ER visits, avoided readmissions, costs of inappropriate referrals.

All statistical analyses will be performed using SPSS 21 or SAS 9.2 for Windows.

Ethics and trial status

Our project is sponsored by the Ministry of Health, Welfare and Sport and ACHMEA. According to Dutch law, this study was exempt of formal medical-ethical approval (METC number 13/142, medical ethical committee UMC Utrecht). For the medical record study we requested an extra assessment by the medical ethical commission. The medical ethical committee Utrecht deemed the record study to be according to Good Clinical Practice; the privacy of the patients is assured (METC-letter - 13-142/C). The TIPP study is on-going. Active data collection started on November 1st 2014 and will run until June 2016.

Discussion

The purpose of this protocol paper is to present the research design and methodology of the TIPP intervention. This trial assesses the effectiveness of a multifactorial complex intervention on transitional patient safety. In addition, it will give more insight into the major risks of transitional care, as well as determinants of successful implementation of a complex intervention. This will result in a matrix to diagnose and improve transitional patient safety that can be broadly implemented.

We faced several methodological challenges during the design of the TIPP trial.

Definitions

The first challenge was to define the concept under study. Terms like continuity of care, integrated care, and transitional care are not well defined in literature and are used interchangeably. Recent initiatives have tried to reach consensus on the definitions and concepts, but results are inconclusive [43]. Table 2 shows the definitions we used in our research. 'Continuity of care' is a very broad multidimensional concept containing personal continuity (within one care-provider), team continuity (within an organisation) and cross-boundary continuity (transitional care) [14]. Integrated care is a strategy to improve patient care which also focuses on processes within and between organisations [44], in which TIPP focuses only on the integration between general practice and hospital (vertical integration). Transitional care applies to actions of healthcare providers between organisations with the patient as the centre which suits the purpose of TIPP to improve care between organisations. In this action, the patient transitions from one organisation to the other. Therefore, we chose to use the term 'transitional care'. With 'transitional patient safety' we refer to patient safety in transitional care.

Design

Of course, the strongest design to evaluate the effect of an intervention is the randomized controlled trial. However, (clustered) randomisation in transitional healthcare creates insolvable problems because involvement of three different stakeholders (hospital, GP and patient). Randomising at each different level of the healthcare chain creates contamination in the other. Also, there is an important risk of contamination when assigning the GPs to a group because of the organisational structure in practices and the collaboration GP groups in the

Table 2 Definitions of expressions used in the protocol

Patient safety	The prevention of errors and adverse effects to patients associated with healthcare [53].
Patient safety incident	A patient safety incident is any unintended or unexpected incident which could have or did lead to harm for one or more patients [54].
Patient safety culture	The safety culture of an organisation is the product of individual and group values, attitudes, perceptions, competencies, and patterns of behaviour that determine the commitment to, and the style and proficiency of, an organisation's health and safety management. Organisations with a positive safety culture are characterized by communications founded on mutual trust, by shared perceptions of the importance of safety, and by confidence in the efficacy of preventive measures [55].
Continuity of care	Either (i) the provision of services that are coordinated across levels of care - primary care and referral facilities, across settings and providers; (ii) the provision of care throughout the life cycle; (iii) care that continues uninterrupted until the resolution of an episode of disease or risk; or (iv) the degree to which a series of discrete healthcare events are experienced by people as coherent and interconnected over time, and are consistent with their health needs and preferences [37].
Integrated care	A concept bringing together inputs, delivery, management and organisation of services related to diagnosis, treatment, care, rehabilitation, and health promotion. Integration is a means to improve services in relation to access, quality, user satisfaction and efficiency [45].
Transitional care	A set of actions designed to ensure the coordination and continuity of healthcare as patients transfer between different locations or different levels of care within the same location [56].
Transitional patient safety	Patient safety at transitions of care.
Transitional incident	Any unintended or unexpected incident at transitions of care which could have or did lead to harm for one or more patients.
Risky situation	Circumstances or events that had the capacity to cause error [57].

region (so-called 'HAGROs'). Because of this assignment problem, interventions in transitional care are usually studied in a non-randomised observational design. Major observational studies on patient safety and transitional care have been criticized on the lack of a control group [45, 46]. Additionally, both settings (hospitals and GP structure) are crucially different in organisation, region and patient care. The participating departments within the three hospitals are different in patient category and risk of transitional incidents. Cluster randomising the hospitals or hospital departments is not possible because they are not comparable. In all, we chose a controlled before-after study design to evaluate the effect of TIPP. For the 'between group' comparisons, we only use surrogate outcomes to improve efficiency. Doing all measurements in the control group would mean that a major part of the intervention was also done in the control situation which would invalidate the control group comparison.

In TIPP, we consciously chose to combine quantitative and qualitative data. Using triangulation of these data helps to clarify the theoretical propositions and the basis of our results. This offers a better understanding of the links between theory and empirical findings [47].

Design of the intervention

TIPP is a multi-faceted intervention containing several components aimed at different areas of transitional safety. Research has shown that an intervention is more effective when aimed at different levels of a process [48–50]. We chose to intervene with the three different stakeholders (hospital, GP and patient), but also within the different facets of transitional patient safety; patient safety culture, the healthcare process and patient participation. The components can also be tailored to the specific wishes of each setting because it is known that implementation of a complex intervention largely depends on context.

Outcome

To capture incidents there are two commonly used methods which both have limitations. The first one is reviewing medical records. The main risk is not recognising the incidents, which can lead to underestimation. The second method is incident reporting. The critical factor is the motivation and time of the healthcare worker (and patient in our study) to actually report events. In our study we decided to apply both methods. Also, the number of incidents reported is ambiguous as both an increase and decrease could indicate an improvement in transitional patient safety. Although one would expect a reduction in incidents, a raised awareness in healthcare will result in an increase in incident reporting. This effect especially shows in healthcare areas where patient safety initiatives are relatively new [51], like transitional care. Because of our relatively short study period, we do not expect to find a reduction during our research.

(3.5) Recruitment

Selecting the proper setting for our study was challenging. We needed both the hospital and GPs in a region to voluntarily participate in our research. Therefore, we chose a convenience sample. This may lead to a selection because it is likely that the most motivated hospital and practices will decide to participate. Of course this selection may lead to overestimation of the effect,

because forerunners may execute the intervention precisely. Underestimation of the effect is also possible because the room of improvement in forerunners op patient safety is smaller. To improve generalizability, we chose to include two very different settings (one rural and one urban, including a university hospital). By developing a context-related intervention, we aim to facilitate broader interest and implementation.

Follow up

TIPP is a complex intervention and may have a diffuse effect which could blur quantitative measurement. The effect usually only manifests after a longer time period [52]. Therefore, we use mixed methods to understand the potential effect.

Strengths and limitations

Summarizing the above-mentioned subparagraphs, our study has limitations caused by the methodological challenges. The TIPP intervention study is an observational study in which we recruited a voluntary convenience sample of regions and hospital departments, which differ in organisation, risks and patient care. This can lead to a selection of participants and either an under- or overestimation of the effect of the intervention. Another limitation is the measurement of the effect of the TIPP intervention. Improvement of transitional safety is difficult to capture in a measurement. Therefore, we chose different measurements for all the three aspects of transitional patient safety: healthcare process, transitional patient safety and patient empowerment. Still, the possibility remains that incidents will be missed.

The TIPP intervention's strength is that it is unique because it involves all patient transitions between hospital and GP and vice versa (referral, discharge and simultaneous GP and outpatient treatment) and is the first to include all direct stakeholders in the transitional process (hospital, GP and patient and their families). It engages in different levels of the transitional process, from patient safety culture through the healthcare process to the patient him/herself. Research has shown that intervening at different levels of a system is more effective than a singular intervention. We implement TIPP in two very different settings, a rural and an urban/academic setting. This will result in additional information on the importance of the context when implementing the intervention. Additionally, we use both qualitative and quantitative methods to provide insight into how the interventions are implemented. By conducting semi-structural qualitative interviews with frontline staff, we will gain a deeper understanding of how the intervention works.

Conclusion

Although the design faced various challenges, TIPP offers a valid scientific evaluation of a structured and integrated approach to improve transitional safety and prevent transitional incidents. Once proven effective, it can be broadly implemented in daily clinical practice.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

DZ and IM initiated the study. MM, HS, AB, NW and DZ designed the study. MM developed the protocol. HS and DZ closely supervised the protocol development. All authors participated in reviewing and editing of various drafts of the manuscript and they all read and approved the final manuscript.

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