Effects of Video-Based Patient Education and Consultation on Unplanned Health Care Utilization and Early Recovery After Coronary Artery Bypass Surgery (IMPROV-ED): Randomized Controlled Trial

INTRODUCTION

1) Problem and the type of system/solution

After discharge, patients commonly experience anxiety or uncertainty about symptoms or appropriate physical exercise [4]. These issues are typically addressed during hospitalization; however, after discharge, patients’ recall of information is often incomplete and they do not always know who to address with questions [4]. The objective of this trial was to fill this knowledge and experience gap. We hypothesized that restructuring the postoperative period with an eHealth strategy would reduce unplanned health care utilization through improved mental and physical health and faster recovery.

METHODS

3a) CONSORT: Description of trial design (such as parallel, factorial) including allocation ratio

The IMPROV-ED trial was a randomized controlled trial (RCT). Patients received either video-based patient education and consultation (intervention group) or standard care (control group).

3b) CONSORT: Important changes to methods after trial commencement (such as eligibility criteria), with reasons

No changes were made to the study protocol between publication and initiation of the trial.

4a) CONSORT: Eligibility criteria for participants

To minimize selection bias, all patients on the waiting list for isolated CABG surgery over 18 years of age were contacted by telephone and informed about the study by one of the investigators. Patients were eligible for participation if they had access to a computer/tablet/mobile phone with internet connection and a webcam/built-in camera; had sufficient knowledge of the use of internet and email (assistance was allowed); and were able to speak, read, and interpret the Dutch language. The eHealth strategy would not be applicable to patients who did not comply with these inclusion criteria and they were therefore not eligible for participation.

4a-i) Computer / Internet literacy

Eligibility criteria for patients included having a computer/tablet/mobile phone with internet connection and a webcam/built-in camera; sufficient knowledge of the use of internet and email (assistance was allowed); and the ability to speak, read, and interpret the Dutch language.

4a-ii) Open vs. closed, web-based vs. face-to-face assessments:

Upon randomization, patients in the intervention group received access to the educational videos via a link sent by email. The same link was sent via email again at discharge. By clicking the link, patients were referred to a hidden (for nonparticipants and the control group) part of the website from the Dutch Heart Foundation that contained the educational videos. The content of the educational videos was constructed and validated by physicians and patient representatives prior to the trial. Based on these evaluations and a scoping review of the literature on delivery of information to patients with varying degrees of health literacy, the full content was delivered to patients at inclusion instead of by fragmented access to videos applicable to the patient’s situation [13]. Nevertheless, to prevent cognitive overload in patients with low health literacy, educational videos were categorized into three categories: treatment (10 videos with information on the surgery and how to prepare for admission), recovery (6 videos about what to expect in the postoperative follow-up in various forms, which have been shown to improve patient outcomes, speed recovery, and reduce health care utilization in various surgical populations [10]). To further enhance the management of patients, eHealth has proven to be of value for patients to enhance their self-management through better understanding of their disease, increased independence, and improved acceptance to adhere to lifestyle advice [3,11]. However, inpatients following CABG surgery is limited, and it remains unclear if eHealth strategies would be effective in this population.

4b) CONSORT: Settings and locations where the data were collected

All patients received questionnaires at inclusion (anxiety subscale of the HADS), at discharge (HADS and RI-10), 1 week after discharge (HADS and RI-10), 2 weeks after discharge (HADS and RI-10), and 6 weeks after discharge (HADS, RI-10, and IMCO). Only the anxiety subscale from the HADS was used. A higher score indicated more favorable progress of recovery (RI-10 maximum score 50). The IMCO resulted in absolute frequencies of visits for the questioned care activities. Patients in the intervention group also received a self-made questionnaire to evaluate the eHealth strategy and to question patients about the use of the educational videos (see Figures S1 and S2 in Multimedia Appendix 1). If patients had not returned the IMCO by 6 weeks postdischarge, the questionnaire was conducted over the telephone. If patients had not returned 2 subsequent questionnaires, a research nurse called patients with a reminder. Questionnaires that were not returned or collected otherwise were considered missing.

4b-i) Report if outcomes were (self-)assessed through online questionnaires

For the assessment of outcomes, a self-made questionnaire was used. If patients had not returned the IMCO by 6 weeks postdischarge, the questionnaire was conducted over the telephone. If patients had not returned 2 subsequent questionnaires, a research nurse called patients with a reminder. Questionnaires that were not returned or collected otherwise were considered missing.

4b-ii) Report how institutional affiliations are displayed

No changes were made to the study protocol between publication and initiation of the trial.

5) CONSORT: Describe the interventions for each group with sufficient details to allow replication, including how and when they were actually administered

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5-x) Access
Upon randomization, patients in the intervention group received access to the educational videos via a link sent by email. The same link was sent via email again at discharge. By clicking the link, patients were referred to a hidden (for nonparticipants and the control group) part of the website from the Dutch Heart Foundation that contained the educational videos.

5-viii) Mode of delivery, features/functionality/components of the intervention and comparator, and the theoretical framework
The content of the educational videos was constructed and validated by physicians and patient representatives prior to the trial. Based on these evaluations and a scoping review of the literature on delivery of information to patients with varying degrees of health literacy, the full content was delivered to patients at inclusion instead of by fragmentized access to videos applicable to the patient's situation [13]. Nevertheless, to prevent cognitive overload in patients with low health literacy, educational videos were categorized in three categories: treatment (10 videos with information on the surgery and how to prepare for admission), recovery (6 videos about what to expect in the postoperative course and when to contact a physician), and healthy living (2 videos on cardiovascular risk management, including smoking cessation, weight reduction, cholesterol management, and exercise). The videos were delivered in spoken text supported by animations for optimal health communication to patients with low and adequate health literacy [13]. Usage data were extracted from the web log for evaluation purposes. Educational videos were available to patients in the intervention group throughout the trial (ie, not only when the link was sent). See the published study protocol for an illustrative overview of the educational videos [11].

6a) CONSORT: Complete defined pre-specified primary and secondary outcome measures, including how and when they were assessed
The primary outcomes of the IMPROV-ED trial were the volume and costs of unplanned health care utilization as defined as a composite of all emergency department visits, outpatient clinic visits, rehospitalization, patient-initiated telephone consultations, and visits to a general practitioner as measured by the Institution for Medical Technologies Assessment Medical Consumption Questionnaire (IMCQ) at 6-week follow-up [14]. Cross-validation with the patients reported health care utilization was performed by contacting their health care providers. The secondary outcomes were the individual unplanned health care activities and a composite of planned and unplanned in-hospital care (emergency department visits, outpatient clinic visits, rehospitalization, and patient-initiated telephone consultations) and planned and unplanned primary care (consultations with a general practitioner, allied health professionals, psychologists) at 6 weeks. The other secondary outcomes were the patients' self-reported physical and mental health, as measured with the Hospital Anxiety and Depression Scale (HADS) and Recovery Index-10 (RI-10) questionnaires [15,16].

6a-i) Online questionnaires: describe if they were validated for online use and apply CHERRIES items to describe how the questionnaires were designed/developed

6a-iii) Describe whether and how "use" (including intensity of use/dosage) was defined/measured/monitored

6b) CONSORT: Any changes to trial outcomes after the trial commenced, with reasons
All patients received questionnaires at inclusion (anxiety subscale of the HADS), at discharge (HADS and RI-10), 1 week after discharge (HADS and RI-10), and 6 weeks after discharge (HADS, RI-10, and IMCQ). Only the anxiety subscale from the HADS was used. A higher score indicated more symptoms of anxiety (HADS maximum score 21) or favorable progress of recovery (RI-10 maximum score 50). The IMCQ resulted in absolute frequencies of visits for the questioned care activities. Patients in the intervention group also received a self-made questionnaire to evaluate the patients' satisfaction and to verify the use of the educational videos (see Figures S1 and S2 in Multimedia Appendix 1). If patients had not returned the IMCQ by 8 weeks postdischarge, the questionnaire was conducted over the telephone. If patients had not returned 2 subsequent questionnaires, a research nurse called patients with a reminder. Questionnaires that were not returned or collected otherwise were considered missing.

7a) CONSORT: How sample size was determined

7b) CONSORT: When applicable, explanation of any interim analyses and stopping guidelines

9) CONSORT: Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned
A certified program was used for sequence generation and randomization (Research Manager).

10) CONSORT: Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions
To minimize bias, all patients on the waiting list for isolated CABG surgery over 18 years of age were contacted by telephone and informed about the study by one of the investigators.

11a) CONSORT: Blinding - If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how
11a-i) Specify who was blinded, and who wasn't
The nurse practitioner/junior doctor who conducted the VCs was blinded to the study's objectives and outcomes. Study participants were not blinded.

11a-ii) Discuss e.g., whether participants knew which intervention was the "intervention of interest" and which one was the "comparator"

11b) CONSORT: If relevant, description of the similarity of interventions not applicable/relevant for study

12a) CONSORT: Statistical methods used to compare groups for primary and secondary outcomes

5-v) Ensure replicability by publishing the source code, and/or providing screenshots/screen-capture video, and/or providing flowcharts of the algorithms used

5-vi) Digital preservation

### RESULTS

| Primary outcomes | Standard care (n=135) | Intervention group (n=136) | Hazard ratio (95% CI) | P value |
|------------------|------------------------|----------------------------|-----------------------|---------|
| OutcomesHealth group | | | | |
| Composite outcomea, n (%) | | | | |

#### Secondary outcomes, n (%)

| Composite unplanned in-hospital care | (26.5) | (39.3) | 0.56 (0.33–0.93) | .026 |
| Emergency department visits | (10.3) | (17.0) | 0.56 (0.27–1.14) | .11 |
| Readmissions | (5.1) | (8.7) | 0.76 (0.28–2.10) | .59 |
| Outpatient clinic visits | (8.1) | (10.7) | 0.45 (0.26–0.78) | .33 |
| Telephonic consultations | (21.3) | (34.8) | 0.51 (0.29–0.87) | .014 |
| General practitioner visits (unplanned) | (30.4) | (30.9) | 0.59 (0.34–0.92) | .022 |

#### Composite outcome

| Composite outcomea, n (%) | 43 (31.6) | 61 (45.2) | 0.56 (0.34 – 0.92) | .022 |

### COSTS

- Cost (Euro), mean (SD): 183 (515) (0-215)
- Cost (Eurob), Median (IQR): 0 (0-95)

#### Secondary outcomes, n (%)

- Composite unplanned in-hospital care: 26.5% (39.3%) 0.56 (0.33–0.93) .026
- Emergency department visits: 10.3% (17.0%) 0.56 (0.27–1.14) .11
- Readmissions: 5.1% (8.7%) 0.76 (0.28–2.10) .59
- Outpatient clinic visits: 8.1% (10.7%) 0.45 (0.26–0.78) .33
- Telephonic consultations: 21.3% (34.8%) 0.51 (0.29–0.87) .014
- General practitioner visits (unplanned): 30.4% (30.9%) 0.59 (0.34–0.92) .022

#### Composite outcome

| Composite outcomea, n (%) | 43 (31.6) | 61 (45.2) | 0.56 (0.34 – 0.92) | .022 |

### COSTS

- Cost (Euro), mean (SD): 183 (515) (0-215)
- Cost (Eurob), Median (IQR): 0 (0-95)
17b) CONSORT: For binary outcomes, presentation of both absolute and relative effect sizes is recommended see answers to previous questions

18) CONSORT: Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from explanatory see supplementary file

18-i) Subgroup analysis of comparing only users

19) CONSORT: All important harms or unintended effects in each group not applicable/relevant for study

19-i) Include privacy breaches, technical problems

19-ii) Include qualitative feedback from participants or observations from staff/researchers

DISCUSSION

20) CONSORT: Trial limitations, addressing sources of potential bias, imprecision, multiplicity of analyses

20-i) Typical limitations in ehealth trials

However, health care utilization is the resultant of a multifactorial behavioral model that attributes a combination of predisposing factors (eg, patient characteristics such as age, sex, sociodemographic parameters, or health literacy and attitude toward health), enabling factors (eg, income, health insurance status, health care organization), and need factors (eg, experience with health care) to health care utilization [28]. The eHealth strategy used in the IMPROV-ED trial has a positive influence on some of these attributes but not all. Interestingly, subgroup analysis showed that the eHealth program had a greater benefit in more vulnerable patients (EuroScore≥2) and revealed a trend toward more benefit in patients with a low level of education. By contrast, a small group of patients who provided informed consent did not use the educational videos or VCs that were part of the eHealth strategy. These patients reported to have received sufficient information from their physician, nurse, or paramedic during admission, or that they found the relevant information online themselves. It might therefore be reasonable to consider adding different modes of digital health delivery to the currently used eHealth strategy (eg, mobile apps, live chat, home monitoring, telerehabilitation) to manage more attributes of health utilization and to offer a more individualized approach tailored to the patients' needs. Combining different modes of digital care might thereby further reduce health care utilization and potentially also improve clinical outcomes [21].

21) CONSORT: Generalisability (external validity, applicability) of the trial findings

21-ii) Generalizability to other populations

22) CONSORT: Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence

The principal finding of the IMPROV-ED trial is that an eHealth strategy comprising educational videos and VCs results in a reduction of unplanned care and costs. In addition, the eHealth strategy is associated with faster patient-reported recovery. These findings are of medical and societal importance given the increasing interest in digital health and the need for value-based alongside evidence-based care. Our study is the first to provide robust evidence that an eHealth intervention can aid in reduction of health care utilization and associated costs. This effect appears applicable to both in-hospital care as well as primary care. One of the most pressing concerns from health care insurance companies and decision-makers toward eHealth is the great investment that is required for development of content and the necessary infrastructure and issues that arise after implementation due to lack of reimbursement options [21].

Our findings refute these concerns by showing positive effects on costs. Furthermore, the eHealth strategy did not only contribute to less patients consuming care (Table 2) but also reduced the care consumed per patient (Table S1 of Multimedia Appendix 1), which underlines the high potential of eHealth strategies for this patient population to also positively influence the burden on health care personnel. With an aging population, a vast increase in health care consumption is expected in the near future. Based on the results of our study, an eHealth program is proven to aid in the sustainment of health care systems.

22-ii) Highlight unanswered new questions, suggest future research

Other information

23) CONSORT: Registration number and name of trial registry

Trial Registration: Netherlands Trial Registry NL8510; www.trialregister.nl

24) CONSORT: Where the full trial protocol can be accessed, if available

A detailed study protocol was published prior to enrollment of the first study participant [11].

25) CONSORT: Sources of funding and other support (such as supply of drugs), role of funders

Funding: not applicable

X26-i) Comment on ethics committee approval

X26-ii) Outline informed consent procedures

X26-iii) Safety and security procedures

X27-i) State the relation of the study team towards the system being evaluated