



Early Results of a Comparative Study of eHealth in Bariatric Surgery

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Abstract

Background: As eHealth has a hypothetical benefit as additional support, there is a widespread implementation in bariatric trajectories. Knowledge about the key components or objective gain is limited. A randomized controlled trial was conducted to assess the value in the bariatric pathway.

Methods: Two-hundred-and-five patients undergoing primary bariatric surgery were randomized to either: Control-group (n=103); online-group (n=50) receiving access to an eHealth platform; or device-group (n=52) who, in addition, received monitoring devices. Here, the 1-year results on convalescence, commitment, eHealth usage and quality of life were assessed.

Results: Median hospitalization was 1 day in all groups. Mean days to return-to-work was 28.1 vs. 27.5 vs. 29.8, respectively, $p=0.673$. Additional physical or telephonic consultations were comparable. Usage of electronic aids, beyond study material, was more frequent in intervention groups. Around 93% of patients used the eHealth platform and approximately half applied the devices regularly. Quality of life improved greatly however did not differ between the groups. Commitment was comparable by questionnaire scores.

Conclusion: The addition of eHealth to a bariatric pathway did not lead to improved outcomes of convalescence, commitment and quality of life one-year postoperatively. There was a trend of higher usage of (electronic) aids in the online- and device-group.

Keywords: Obesity; Bariatric surgery; eHealth; Telemedicine

Introduction

Bariatric surgery is considered the best currently available treatment option for long-term weight loss and sustainability compared to conservative treatment [1]. Adequate weight sustainability and prevention of weight regain poses a challenge for the bariatric team. Undesirable outcomes of surgery, such as insufficient weight loss, nullifies the investments made by patients and the treatment team. Patient selection, an experienced bariatric team and an adequate follow-up program are key elements to success [2,3]. Adherence to such a postoperative program is important to be able to guide patients in lifestyle modifications which are required after an operation (e.g. dietary instructions, vitamin intake, engaging in physical activity and more), but also to signal postoperative complications (malnutrition, psychological problems, and more). Efforts are required to ensure patients stay committed to throughout the whole treatment trajectory.

Access to electronic devices, web access and digitalization are becoming increasingly ingrained in modern society, including health care. This can create opportunities to enhance clinical outcomes, patient's experiences and adherence to the postoperative program. It can be hypothesized that adding eHealth to standard of care can have positive effects on clinical outcomes. Usage of eHealth has shown to have an additional positive effect on weight loss [4]. Furthermore, faster Return to Work (RTW) was seen after gynecological surgery with addition of eHealth [5,6]. An early randomized controlled trial found that adding eHealth solutions to standard of care in bariatric surgery can lead to more weight loss at one and two years postoperatively [7]. However, a recent systematic review about the value of eHealth in bariatric surgery concluded that literature about eHealth usage in bariatric surgery is still scarce [8]. To our knowledge, no randomized, prospective study has been conducted that analyzes the effect of eHealth and digital self-monitoring devices in

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bariatric surgery.

A comparative study was conducted in a large bariatric center in the Netherlands to assess the value of different levels of eHealth. In present paper RTW, length of stay, rate of eHealth usage, commitment and Health Related Quality of Life (HRQoL) outcomes at one year postoperatively are discussed.

Materials and Methods

The study with a randomized controlled design was conducted in a large teaching hospital in the Netherlands. It was named after the eHealth platform used: The BePatient trial and started in February 2017 after medical ethical approval. The protocol was registered (NTR6827 and NL56992.100.16) and has been published before [9]. In summary, patients with a team approval for primary sleeve gastrectomy or gastric bypass conform the criteria of the International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) [10] with the ability to use the provided patient platform with ongoing access to the internet and Smartphone or tablet were considered eligible for the study. They were informed at least twice during the preconditioning program by oral and written presentations by members of the research team or bariatric surgeons. In case of inclusion after signed informed consent, they were randomized in a 2:1:1 ratio by a computer. These groups were (A): Control-group (n=100), who received standard of care; (B) online-group (n=50), who received access to an eHealth platform (detailed description below) in addition to standard of care; and (C) device-group (n=50), who received access to the platform and four telemonitoring devices (detailed description below) in addition to standard of care. Inclusion was continued based on availability of devices. The follow-up period for this study was two years postoperatively.

Intervention arms

Patients in the control-group received standard of care consisting of a five-year follow-up trajectory. In the first year after the operation, patients attend normally at least 13 consultations with a bariatric surgeon, obesity nurse, dietician, psychologist and physiotherapist, of which three are in group session. The frequency of visits including medical check with blood samples is then reduced in the following years or increased upon request. All patients received a personalized booklet on their follow-up program.

In the online-group, the access to an eHealth platform in addition to standard of care was added. An institutional-specific platform was tailored in collaboration with a digital health solutions company (SAS BePatient, Paris, France). Patients received personal accounts which they could use to access the platform either on a mobile device or computer. The platform was accessible by web browser or app. The platform contained up-to-date information about obesity, videos about procedures, preparation tips, factsheets, dietary and lifestyle tips, question-of-the-week and frequently asked questions. The content was regularly updated. Patients were also able to ask for continuation of their medication, post questions and remarks on the forum and chat with other patients.

Patients in the device-group received wireless monitoring devices, on top of the programs described above. A digital weight scale, blood pressure monitor, oxygen saturation meter and activity bracelet were connectable to a mobile phone or tablet by Bluetooth. Measurements were stored on the patients' personal platform accounts and meant for insights in their own health status. The research team was

provided read-only access by the patient and provided support in case of questions or malfunction of devices.

Outcome measures

The primary outcome measure for this trial was weight loss at two years postoperatively. In the present paper the assessment of secondary outcome measures up to one year after the surgery was reviewed. Included were length of stay (LOS, beyond standard one day was considered extended LOS), days to return to work (assessed by questionnaire at 6 weeks) and satisfactory and commitment to the follow-up program assessed with a non-validated questionnaire at one year postoperatively. The latter one included an evaluation of the aftercare program in a 0 to 10 score and 6 yes-or-no questions about whether patients felt committed to the aftercare program. Furthermore, usage of eHealth solutions and devices other than provided for the study was assessed at one year postoperatively with a questionnaire and data traffic on the platform was collected. Lastly, HRQoL was measured using the Rand-36 questionnaire at baseline and each year postoperatively [11,12].

Descriptive statistics of the data was performed for all baseline characteristics and outcome measures. Groups were compared using χ^2 -tests, ANOVA-tests (normal distribution) or Kruskal Wallis U-tests (non-normal distribution) to analyze outcome measures. SPSS Statistics version 25 (IBM Corp., Armonk, NY, USA) was used for statistical analysis and handling of data. Analysis was performed using the intention-to-treat principle. A p-value <0.05 (two-sided) was considered statistically significant.

Results

Two-hundred-and-five patients were included who underwent either a sleeve gastrectomy (n=130) or gastric bypass (n=73). Their baseline characteristics are shown in Table 1. During the first year of the study a total of 14 subjects quit participating in the trial. In the control-group 3 patients really wanted to have access to the platform and 1 quitted the program. Same number of patients discontinued to participate in the online-group; due to unrelated health problems (n=1); not willing to use the platform (n=1) and 2 no-shows. Most losses were in the device-group (n=8). Half of them was related to the devices; the measurements made them feel insecure (n=3) or they could not successfully connect devices (n=1). The rest of the no-shows were due to emigration (n=1), unrelated health problems (n=1) and unknown reasons (n=2).

There was no difference in length of stay (p=0.467) nor in proportion of extended stay (p=0.467 (Table 2). After surgery, 16% of all subjects required additional outpatient department visits (equally distributed, p=0.500). Additional telephonic consultations were more abundant with 56% of all subjects requiring additional telephonic consultations. This was also not statistically different between groups (p=0.929).

The days to RTW outcomes were based on all questionnaires (205/205). The employment rate was 79%. The distribution of work status after 6 weeks was not statistically different between intervention groups, p=0.673. The percentage of patients whom fully RTW was 44% in the control-group, 30% in the online-group and 37% in the device-group, the mean number of days to reach RTW was 28.1, 27.5 and 29.8 (p=0.681), respectively. Commitment and adherence to the program were rated by questionnaires (Table 2). In the normal-group, the postoperative trajectory scored a mean of 8.4 out of 10,

Table 1: Baseline characteristics.

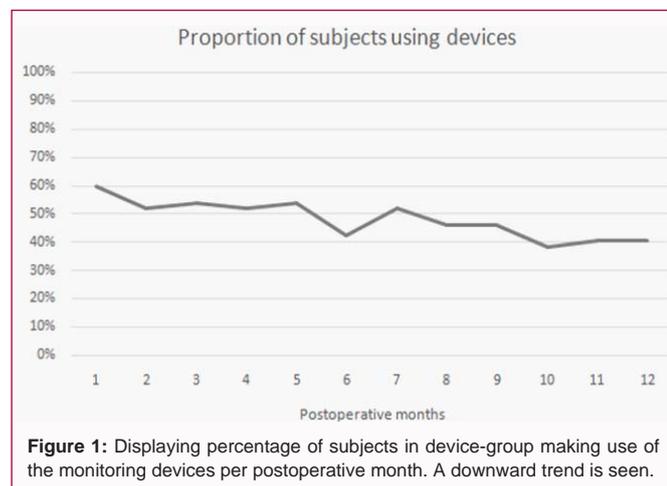
	Control (n=103)	Online (n=50)	Device (n=52)
Gender, male: female (n)	27:76	12:38	09:43
Mean BMI, SD, kg/m ²	41.9 ± 4.3	42.0 ± 5.7	42.3 ± 4.6
Mean age, SD, years	45.0 ± 10.5	46.2 ± 10.5	43.1 ± 10.9
Age range, years	23-65	26-65	21-60
Procedure, SG: RYGB, N	66:37:00	33:16:00	31:20:00
Mean N of comorbidities, SD	1.8 ± 1.3	2.2 ± 1.3	1.8 ± 1.2

Abbreviations: BMI: Body-Mass Index; SG: Sleeve Gastrectomy; RYGB: Roux-en-Y Gastric Bypass
Age is defined at time of surgery

Table 2: Hospitalization, additional visits in the first postoperative year, return to work and commitment questionnaire after 1 year.

	Control (n=103)	Online (n=50)	Device (n=52)	p
Hospitalization				
Length, days, median [IQR]	1 [1-1]	1 [1-1]	1 [1-1]	0.467
≥ 2days, %, (n=)	15% (15)	22% (11)	14% (7)	0.42
Additional visits				
Outpatient visits, %, (n)	19% (19)	14% (7)	12% (6)	0.5
Telephonic consults, %, (n)	56% (57)	55% (27)	59% (30)	0.929
Return to work questionnaire:				
Not returned yet, %, (n)	19 (19)	30 (14)	19 (9)	0.673
Partially returned, %, (n)	15 (15)	17 (8)	21 (10)	
Fully returned, %, (n)	44 (44)	33 (15)	40 (19)	
Unemployed, %, (n)	23 (23)	20 (9)	21 (10)	
Days till full RTW, mean	28.1	27.5	29.8	0.681
Commitment questionnaire:				
Score for program, 0-10, mean	8.4	7.8	7.8	0.149
Positive answers, out of 6, mean	4.8	4.5	4.3	0.164

Abbreviations: IQR: Interquartile Range; RTW: Return to Work.



compared to 7.8 in both online- and device-group ($p=0.149$). The mean number of positive adherence answers (corresponding to a feeling of commitment and adherence) was 4.8 vs. 4.5 vs. 4.3 out of 6 questions in normal-, online- and device-group, respectively ($p=0.164$). No relevant differences in separate answers were seen besides that 40% in the device-group felt not involved to the program compared to 16% in the normal-group, $p=0.013$.

More than 93% of the patients actually used the platform (Table 3). The mean number of connections to the platform was 17 for

the online-group and 33 for the device-group ($p=0.035$), and the mean number of page views was 91 and 82 respectively ($p=0.855$). The most visited contents were the 'Preparation phase'-section and 'Lectures about obesity' -section, followed by Frequently-Asked-Questions. In terms of weekly usage of additional support, significant more usage of web-based support (other than the provided eHealth platform) was seen in the eHealth group (online- and device-group) with only 1 patient using other web-based solutions in the control-group compared to 13 in the eHealth groups ($p=0.010$). Also, more subjects in the eHealth groups used other media (forums, social media, etcetera) compared to the control-group although this was not statistically significant ($p=0.069$). The usage of devices to support weight loss was also not statistically different between groups, although a blood pressure and oxygenation monitor were barely used in the control-group. Over time, the percentage of usage of devices declined from around 60% to 40% in the last months of the first postoperative year (Figure 1). A total of 47 out of 52 subjects in the device-group contacted the research team at least once during the first year of this trial because of technical issues with the monitoring devices. This was due to: connection problems ($n=36$); problems with the activity tracker ($n=19$); blood pressure cuff being too big ($n=8$); and problems with the weight scale ($n=2$).

HRQoL improvement after one year postoperatively is shown in table 4. Overall HRQoL after one year was very high. Across all domains in all groups major improvements were seen. No statistically significant differences were seen between groups.

Table 3: Commitment questionnaire, usage of eHealth and usage of additional support, assessed after one year. The eHealth group consisted of the online-group and device-group combined.

Usage of eHealth platform	Control	Online	Device	p
Used platform (%)	-	90%	96%	0.219
Mean number of connections	-	17	33	0.035
Mean number of page views	-	91	82	0.618
Mean page views in: Preparation phase	-	21	21	0.959
Lectures about obesity	-	21	20	0.925
Frequently-asked-questions	-	13	13	0.863
Videos about procedures	-	11	11	0.964
Question of the Week	-	11	7	0.313
Fact or Fiction	-	4.5	1	0.065
Tip of the week	-	3.3	3.2	0.956
Sports program	-	0.5	0.8	0.589
Patients' experience	-	0.7	0.2	0.206
Prevention of weight regain	-	0.3	0.6	0.26
Additional support questionnaire	Control	eHealth		p
Percentage of patients that used the following weekly:				
Internet site, other than intervention platform	1	13		0.01
Other media (forums, social media)	11	23		0.069
Gym or sports center	64	66		0.768
Mobile application for recipes/dietary support	7	11		0.11
Mobile application for exercise support	24	21		0.694
External coach/psychologist	8	8		0.901
Weight scale	78	81		0.658
Activity tracker	33	41		0.381
Blood pressure monitor	1	7		0.117
Oxygenation monitor	0	5		0.117

Table 4: Quality of life improvement at 1 year compared to preoperative results.

	Control (n=70)	Online (n=28)	Device (n=24)	p
	Mean ± SD	Mean ± SD	Mean ± SD	
Physical functioning	34.9 ± 19.0	32.7 ± 24.3	33.1 ± 18.9	0.857
Social functioning	22.5 ± 25.1	23.2 ± 27.8	20.3 ± 25.5	0.913
Physical role impairment	48.6 ± 42.1	40.2 ± 43.2	41.7 ± 47.6	0.622
Emotional role impairment	40.5 ± 45.7	35.7 ± 48.8	38.9 ± 46.8	0.901
Mental health	12.0 ± 14.8	7.71 ± 15.6	13.3 ± 14.1	0.332
Vitality	22.2 ± 21.4	25.5 ± 20.6	19.2 ± 15.5	0.526
Pain	29.4 ± 26.1	28.9 ± 32.4	32.9 ± 24.7	0.84
General health perception	35.1 ± 19.6	34.3 ± 20.5	31.8 ± 20.7	0.788
Health change	58.6 ± 26.2	60.7 ± 24.9	54.2 ± 34.3	0.678
Cumulative improvement score	303.8 ± 155.7	289.0 ± 160.1	285.4 ± 166.6	0.85

Discussion

Literature is scarce on the clinically relevant benefits of eHealth to bariatric treatment. These early results of the BePatient-trial have not shown that integration and effect of eHealth in the bariatric pathway has clinically relevant benefits on the short term. No clinically significant differences were seen between intervention groups in terms of baseline characteristics, hospitalization length, RTW, involvement in the program and HRQoL in this trial.

It was hypothesized that more informed patients are better prepared and might feel more secure about what to expect after surgery and could be discharged earlier from the hospital and might need less help, and therefore less additional consultations. The results of this trial did not retain this hypothesis as no differences were seen between groups.

The addition of eHealth could also be beneficial for faster RTW after surgery, as others found in studies on patients undergoing

gynecological (hysterectomy or laparoscopic adnex surgery) [5,6]. This was not supported by the results of this study. Days to RTW ranged widely, from 1 day to more than 6 weeks after the operation. Even at 6 weeks postoperatively, 37% of employed patients did not RTW yet. Numerous reasons were given for this. Most subjects claimed extra days off work for further recovery, however, commented that they could get back to work earlier if they needed to. An explanation for these conflicting results could be that the platform was not focused on promoting sooner RTW and sick leave period sometimes depend on the company's regulations.

Contrary to what was expected, patients in the device-group commented that they felt less involved to the program compared to patients in other groups. Those patients also scored lower in 'willingness to put effort in the program' and 'feeling that they could easily quit the program', however this was not statistically significant. Some patients in the device-group commented that doing the measurements was more of a burden than an opportunity for them to gain insight in their progress. So, while the purpose of the devices was to encourage patients to be more conscious about their health, and thereby improving commitment and willingness to put effort in the program, the opposing effect was seen. This could also have influenced an unexpected high percentage of subjects quitting the study early. In addition, almost all patients in the device-group contacted the research team at least once due to technical issues (failure to log on, to connect or download). In Figure 1 the percentage of subjects adequately using the acquired devices are displayed. At the start of the trial, just 60 percent of all subjects are using the devices and this decreased to around 40 percent at one-year postoperatively. This can indicate that not all patients are willing to use electronic devices to give insights in their own health status on a regular basis, even though participants were enthusiastic at the time of inclusion. The feedback the treating team received from those, who claimed to regularly use the platform or devices, was that they felt it was a great addition to standard of care. On the other hand, for a few patients, the measurements made them feel insecure about their well-being and looked subsequently for more (primary) care. These findings suggest that a more personal approach might be important and that these interventions might be only beneficial to specific groups.

The perception of the addition of eHealth to a standard health program is not yet clear. Van der Meij et al. found that some patients experienced eHealth as an addition to the usual care, however, also found low usage of the offered intervention [13]. For instance, 64% made use of the activity tracker, 50% used the app and only 7% made use of an E-consultation. Reasons for this were that patients did not see advantages or experienced technical issues. The platform usage in the present trial was very high. More than 93% of subjects used the platform at least once during the first year of this trial. Data traffic results show that General information; Videos and Question-of-the-Week were among the most frequently visited subtypes of content. Subjects commented that the platform fulfilled their desire for easy and comprehensive information.

The addition of eHealth can have positive effects on QoL as well. A systematic review on eHealth usage by breast cancer patients concluded that multi-component eHealth systems seem more effective (e.g. social support system, mobile apps, monitoring) [14]. Literature on the value of eHealth on HRQoL outcomes in bariatric surgery is scarce and results vary [15-17]. HRQoL improved drastically at one year after the operation, as literature suggests

[18,19]. Across all domain's improvement was seen, however, no differences between intervention groups. An explanation for this could be that potential small differences cannot be detected because of the major improvement seen at one year postoperatively regardless of intervention group. It is possible that eHealth usage can be beneficial in maintaining a high HRQoL. Longer term studies must be conducted to test this hypothesis.

Limitations of this study should be addressed. It can be expected that patients will make use of other eHealth solutions or gather information on the Internet as this is becoming widely available. In addition, some patients in the eHealth groups did not utilize the platform or devices. In an intention-to-treat analysis this bias should be minimal and reflect daily practice. Another limitation of this trial is the high number of patients who quit the study early, as mentioned before. This, however, is also a valuable finding. Future assessment is needed to determine if patients are willing to make use of eHealth solutions, if the interventions are only beneficial for a specific subset of patients, or if eHealth is an unwanted addition to standard of care.

Conclusion

The value of eHealth, in particular in bariatric surgery, is not investigated broadly. It was hypothesized that the addition of eHealth to standard of care can be beneficial. Early results of the BePatient-trial have shown no clinically significant differences in terms of convalescence after surgery, RTW, commitment to the program and quality of life at one year postoperatively. There was a tendency for usage of more (electronic) aids in the online- and device-group. Longer term results and weight loss outcomes will be published in the future.

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Institutional Review Board Statement

The study was approved by the institutional medical ethical board and was conducted conforming the principles of Good Clinical Practice and the Declaration of Helsinki.

Trial Registry

The study was approved by the institutional medical ethical board and was conducted conforming the principles of Good Clinical Practice and the Declaration of Helsinki. The protocol was registered to the Dutch Trial Registration (identifier number NTR6827) and to ClinicalTrials.gov (identifier number NL56992.100.16).

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