# Headache patients' satisfaction with telemedicine: a 12-month follow-up randomized non-inferiority trial

K. I. Müller[a,b] (iD), K. B. Alstadhaug[a,c] and S. I. Bekkelund[a,b]

[a]*Department of Clinical Medicine, UiT – The Arctic University of Norway, Tromsø;* [b]*Department of Neurology, University Hospital of North Norway, Tromsø; and* [c]*Department of Neurology, Nordland Hospital Trust, Bodø, Norway*

**Background and purpose:** We investigated non-acute headache patients' long-term satisfaction with a telemedicine consultation and consultation preferences in northern Norway. We hypothesized that patients were not less satisfied with telemedicine than traditional consultations. We also examined the influence of gender, age and education on satisfaction.

**Methods:** For 2.5 years, patients were consecutively screened, recruited and randomly assigned to telemedicine or traditional visits with a consultation at a neurological outpatient department. The primary endpoint was frequency of satisfied patients at 3 and 12 months. Secondary endpoints were satisfaction with consultation, communication, information, diagnosis, advice and prescriptions, and preferred visit form at 12 months.

**Results:** Of 402 participants, 279 (69.4%) answered questionnaires at both 3 and 12 month, and 291 (72.4%) responded at 12 months. The long-term satisfaction of telemedicine patients was 124/145 (85.5%) compared with 118/134 (88.1%) in the traditional group ($P = 0.653$). The groups did not differ with respect to secondary endpoints, but females were more satisfied with telemedicine communication ($P = 0.027$). In the telemedicine group, 99/147 (67.3%) were indifferent to the type of consultation. Age and education did not alter the primary results.

**Conclusions:** At 1 year after a specialist evaluation for headache, telemedicine patients did not express less satisfaction than those with traditional consultation. Telemedicine specialist consultations may be a good alternative for headache patients in secondary care.

## Introduction

A well-educated woman in her 50s travelled 800 km to a headache specialist consultation [1]. She complained about the long journey, being absent from home and work, and not being able to care for her grandchild. She asked why this travel was necessary, as the consultation could be done remotely through telemedicine. Similar experiences are reported by many headache patients in our large and sparsely populated area (Figure S1), and were an important motivation for this project [2].

The wide use of telemedicine in clinical practice [3] and limited evidence to recommend use of information and communication technology in the management of headache justify a randomized trial [4–7]. Moreover, telemedicine may help combat misdiagnoses, delay and suboptimal treatment of headaches [1,8–10], but we need to ensure that new technology keeps up with diagnostic quality and good clinical practice.

We investigated non-acute headache patients' long-term satisfaction with a telemedicine consultation and consultation preferences. Additionally, we assessed how sex, age and education influenced patients' satisfaction with telemedicine. The primary hypothesis was that telemedicine is not inferior to traditional

Correspondence: K. I. Müller, Department of Neurology, University Hospital of North Norway, N-9038 Tromsø, Norway (tel.: +47 776 27073; fax: +47 776 27074; e-mail: kai.ivar.muller@unn.no).
The copyright line for this article was changed on 22 May 2017 after original online publication.

visits in non-acute headache patients' long-term satisfaction.

## Patients and methods

### Participants, design and setting

All patients were consecutively recruited from September 2012 to March 2015 from referrals to our secondary neurological outpatient department (Fig. 1). Participants randomized to the traditional group had an in-person consultation in the examination rooms by a neurologist (K.I.M. or S.I.B.). Participants in the telemedicine group had a consultation via a system that provided a two-way audio and video communication between the neurologist in the examination room and the patient in the videoconference room [2,11]. All participants received a one-time consultation and a 3- and 12-month follow-up questionnaire.

The eligibility criteria were males and females aged 16–65 years with non-acute headaches referred from general practices in northern Norway (Figure S1), waiting time less than 4 months, and patients not being consulted by neurologist for headache in the previous 2 years. Those with abnormal findings on neurological examination reported by the referring doctor or by neuroimaging, suggestive of a secondary headache cause, were excluded.

### Questionnaire

The questionnaire was sent, by patient preference, either by letter or via internet survey [12]. A reminder was sent if no answer was received within 2 weeks.

At 12 months patients were asked:
(a) If they were 'satisfied with the consultation' ('Yes'/'No').
(b) If they were satisfied with the information at the specialist consultation ('Yes'/'No').
(c) If they were satisfied with the diagnosis at the specialist consultation ('Yes'/'No').
(d) If they were satisfied with the advice given at the specialist consultation ('Yes'/'No').
(e) If they were satisfied with the medication prescribed at the specialist consultation ('Yes'/'No').
(f) If they were satisfied with the communication at the specialist consultation ('Yes'/'No').
(g) If they, based on their previous experience 12 months earlier, would prefer a specific type of consultation ('Traditional consultation', 'Telemedicine consultation' or 'No preferences').
(h) If they were satisfied with the general practitioner's (GP) headache treatment and follow-up after the headache specialist consultation ('Yes'/'No').

### Outcome variables

To minimize confounders and to standardize the conditions, we obtained data of patient satisfaction from the 3-month questionnaire. Subsequently, in order to obtain a more dynamic perspective of satisfaction, we defined patients who were satisfied with the baseline consultation at both 3 and 12 months as the primary outcome variable.

Primary outcome:
(a) Frequency of satisfied patients at 3 months who confirmed satisfaction at 12 months (pre-specified).
Secondary outcome at 12 months:
(b) Frequency of satisfied patients (pre-specified).
(c) Frequency of patients who were satisfied with communication, information, diagnosis, advice and medication (non-pre-specified).
(d) Frequency of telemedicine patients who preferred traditional consultation compared with patients who were either indifferent or preferred telemedicine (non-pre-specified).
(e) Frequency of patients who were satisfied with the GP's treatment and follow-up (non-pre-specified).
(f) A non-pre-specified *post hoc* analysis to evaluate impact of sex, age and education on patients' satisfaction with telemedicine consultations.

### Sample size and randomization

Sample size estimation was based on a satisfaction frequency of 90%. If there is no difference between the two groups, then 254 participants are needed to be 95% sure that the upper limit of a one-sided 99% interval (or equivalently a 98% two-sided confidence interval) will exclude a difference in favour of the traditional consultation [13]. We estimated that 400 patients at baseline were required to achieve valid 12-month data. The Research Department at Tromsø University Hospital administered the randomization. Participants were randomized by using an *Rnd* function in Microsoft Access [2,11].

### Statistical analysis

We used SPSS 23 (IBM Corp, Armonk, New York, USA) to analyse the data. Cronbach's alpha tested for internal consistency of categories of satisfaction in the 12-month questionnaire. Continuous variables were tested for normal distribution with skewness, kurtosis and visual inspection of histograms. Continuous variables are given as mean (SD) and groups were compared by using $t$-test and chi-square (categorical variables). Intention-to-treat (ITT) analysis was performed by adding missing values to the cross-
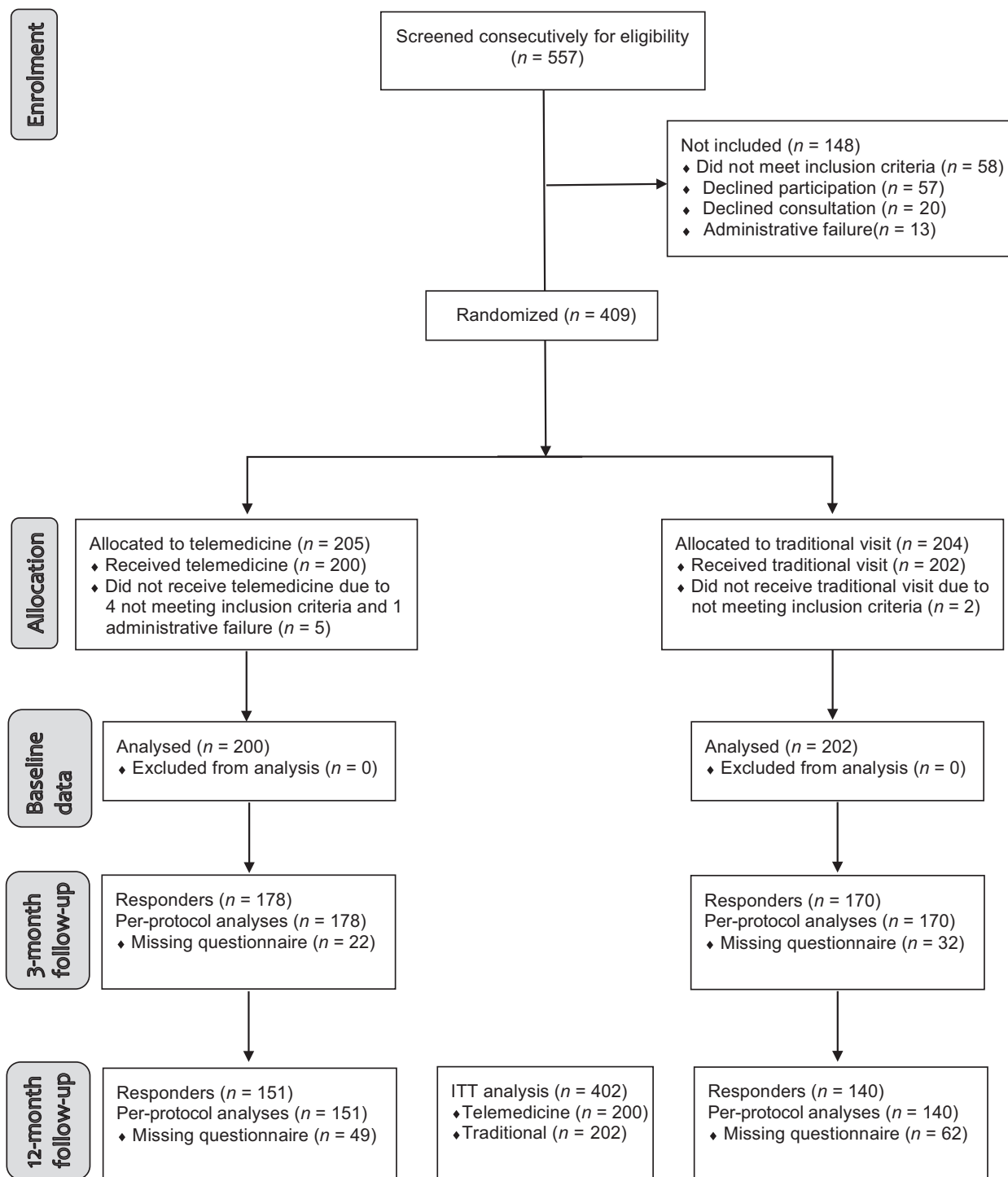
**Figure 1** Flow of participants through the study. ITT, intention-to-treat.

tabulation. Baseline characteristics of non-respondents were compared with respondents, and baseline characteristics of the randomized groups were compared between non-respondents at 3 and 12 months (dropout analysis). Age was categorized into 25, 50, 75 and 100 percentiles as part of the *post hoc* analysis. Pre-specified and non-pre-specified outcome variables are defined in the Patients and methods and Results

sections. A minimal clinical significant change of Headache Impact Test 6 (2.3) and visual analogue pain scale (1.3) has been defined [14,15]. To ascertain similar treatment outcomes, we compared minimal clinical significant change of Headache Impact Test 6 and visual analogue pain scale from 0 to 12 months between the two groups (Table 3).

### Consent and ethical approval

Oral and written information were given to all participants, and consent forms obtained before data collection. The participants' privacy and integrity were respected in accordance with the Helsinki Declaration [16]. The Norwegian National Committee for Medical and Health Research Ethics (REC) approved the study (NR.2009/1430/REK). It was first registered at the Norwegian Research and Management database (FAS.ID3897/HST959-10) [17], and later at ClinicalTrials.gov (ID.NCT02270177).

## Results

Of the 402 participants, 279 (69.4%) answered both questionnaires. Of the 145 respondents in the telemedicine group, 124 (85.5%) were satisfied, 9 (6.2%) were dissatisfied, 5 (3.4%) changed from dissatisfied to satisfied and 7 (4.8%) changed from satisfied to dissatisfied (Fig. 2) at 12 months. Of the 134 respondents in the traditional group, 118 (88.1%) were satisfied, 6 (4.5%) were dissatisfied, 4 (3.0%) changed from dissatisfied to satisfied and 6 (4.5%) changed from satisfied to dissatisfied (Fig. 2) at 12 months. Cronbach's alpha of overall satisfaction, communication, information, diagnosis, advice and medication was 0.82.

Baseline characteristics of all participants and those answering the 12-month questionnaire were balanced between the randomized groups (Table 1). At 3 months, those who answered the questionnaire were marginally older than the non-responders ($P = 0.062$), and at 12 months responders were older than non-responders ($P = 0.020$) (Table S1–S2). We found no other differences between responders and non-responders at 3 and 12 months ($P > 0.05$) (Table S1–S2). Apart from a larger proportion of women among non-responders in the traditional group at 12 months ($P = 0.023$), baseline characteristics of non-responders were balanced between the randomized groups (Table S3–S4).

Table 2 shows baseline characteristics and comparisons between the genders. Table 3 summarizes per-protocol and ITT analyses of the frequency of satisfied patients (pre-specified) and the frequency in
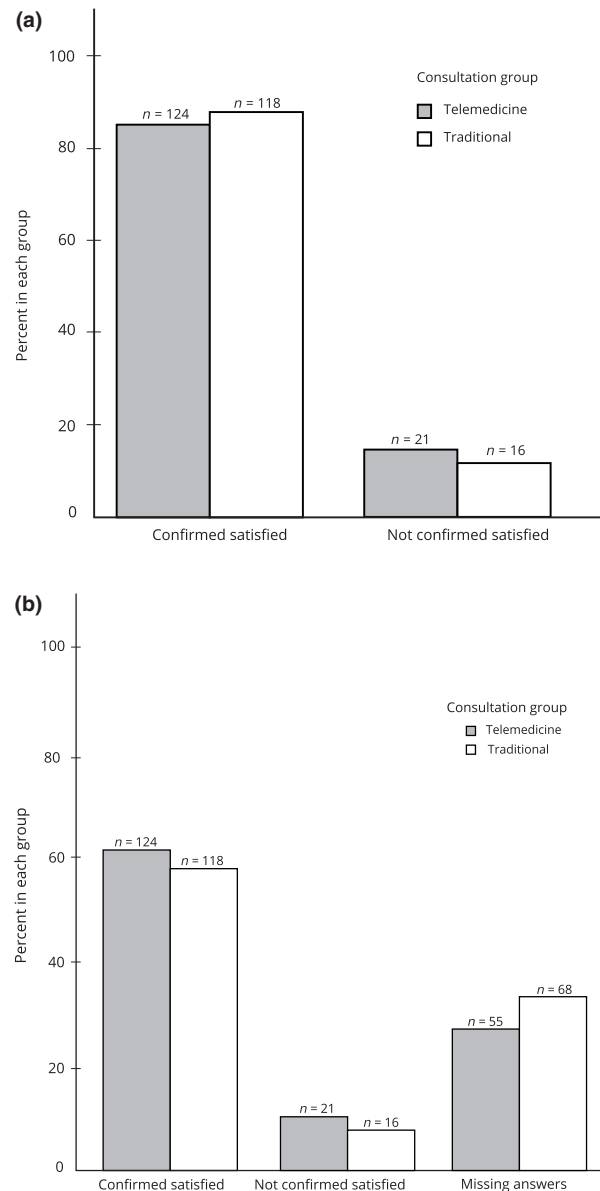
**Figure 2** Comparison of patients who confirmed satisfaction at 3 and 12 months. (a) Per-protocol analysis ($n = 279$, $P = 0.653$). (b) Intention-to-treat analysis ($n = 402$, $P = 0.335$). ▣, telemedicine; □, traditional.

subgroups of satisfaction (non-pre-specified). Table 4 shows a non-pre-specified subgroup analysis of headache patients who underwent telemedicine, comparing those who were indifferent to the form of consultation and those who preferred traditional consultations.

There were no differences in combined satisfaction, overall satisfaction, communication, information, diagnosis, advice, prescriptions, GP treatment and follow-up at 12 months between the age categories (16–25, 26–36, 37–47 and 48–65 years, $P > 0.05$). Compared with those with only primary school/high school

**Table 1** Baseline characteristics of non-acute headache patients who had a consultation at a neurological outpatient department and were followed up 12 months later

| | All participants | | | Patients answering 12-month questionnaire | | |
|---|---|---|---|---|---|---|
| | Telemedicine ($n$ = 200) | Traditional ($n$ = 202) | $P$-value | Telemedicine ($n$ = 151) | Traditional ($n$ = 140) | $P$-value |
| Demographics | | | | | | |
| Age (years) | 36.0 (13.0) | 38.0 (13.7) | 0.124 | 36.7 (13.2) | 39.3 (14.2) | 0.096 |
| Females | 148 (74.0) | 153 (75.7) | 0.774 | 119 (78.8) | 103 (73.6) | 0.362 |
| Males | 52 (26.0) | 49 (24.3) | | 32 (21.2) | 37 (26.4) | |
| Level of education | | | | | | |
| Primary/high school | 128 (64.0) | 122 (60.4) | 0.521 | 95 (62.9) | 84 (60.0) | 0.697 |
| College/university | 72 (36.0) | 80 (39.6) | | 56 (37.1) | 56 (40.0) | |
| Clinical characteristics | | | | | | |
| BMI (kg/m$^2$) | 27.1 (5.4) | 26.9 (5.3) | 0.617 | 27.1 (5.4) | 27.5 (5.4) | 0.505 |
| Systolic bp (mmHg) | 129.8 (16.5) | 130.0 (17.1) | 0.903 | 130 (16.9) | 131 (17.9) | 0.571 |
| Diastolic bp (mmHg) | 80.9 (11.6) | 80.6 (11.8) | 0.794 | 81 (11.8) | 80.8 (12.4) | 0.769 |
| Without comorbidity | 115 (57.5) | 106 (52.5) | 0.362 | 90 (59.6) | 74 (52.9) | 0.298 |
| Headache characteristics | | | | | | |
| Age at headache onset (years) | 24.5 (14.4) | 25.4 (14.3) | 0.533 | 24.4 (14.6) | 26.6 (15.2) | 0.203 |
| HIT-6 | 64.1 (6.1) | 64.0 (6.1) | 0.824 | 63.7 (6.3) | 63.7 (6.1) | 0.988 |
| VAS | 7.1 (2.2) | 6.9 (2.1) | 0.492 | 7.0 (2.2) | 6.9 (2.0) | 0.716 |
| Headache attacks >4 h [19] | 164 (82.0) | 172 (85.1) | 0.473 | 124 (82.1) | 122 (87.1) | 0.307 |
| Headache days/month [19] | | | | | | |
| >15 days | 120 (60.0) | 113 (55.9) | 0.469 | 87 (57.6) | 76 (54.3) | 0.650 |
| <15 days | 80 (40.0) | 89 (44.1) | | 64 (42.4) | 64 (45.7) | |
| Migraineur | 156 (78.0) | 158 (78.2) | 1.000 | 116 (76.8) | 108 (77.1) | 1.000 |

Data are presented as mean (SD) or number (%). BMI, body mass index; bp, blood pressure; HIT-6, Headache Impact Test-6 [18]; VAS, visual analogue pain scale (0 = no pain, 10 = worst possible pain) [15].

**Table 2** Baseline gender comparisons of non-acute headache patients who had a consultation at a neurological outpatient department and were followed up 12 months later

| | Baseline | | | Patients answering 12-month questionnaire | | |
|---|---|---|---|---|---|---|
| | Men | Women | $P$-value | Men | Women | $P$-value |
| Gender | 101 (25.1) | 301 (74.9) | | 69 (23.7) | 222 (76.3) | |
| Age (years) | 40.6 (13.7) | 35.8 (13.1) | **0.001** | 42.9 (14.0) | 36.4 (13.3) | **0.001** |
| Level of education | | | | | | |
| Primary/high school | 80 (79.2) | 170 (56.5) | **< 0.001** | 53 (76.8) | 126 (56.8) | **0.004** |
| College/university | 21 (20.8) | 131 (43.5) | | 16 (23.2) | 96 (43.2) | |
| Education (years) | 13.1 (2.8) | 13.9 (3.1) | **0.022** | 13.1 (3.1) | 13.8 (3.0) | 0.077 |
| BMI (kg/m$^2$) | 27.8 (4.5) | 26.7 (5.5) | 0.092 | 28.5 (4.5) | 26.9 (5.6) | **0.031** |
| Obesity (BMI ≥ 30) | 29 (28.7) | 72 (23.9) | 0.407 | 24 (34.8) | 57 (25.7) | 0.187 |
| Without comorbidity | 48 (47.5) | 173 (57.5) | 0.104 | 30 (43.5) | 134 (60.4) | **0.020** |
| Chronic neck pain | 43 (42.6) | 145 (48.2) | 0.389 | 29 (42.0) | 102 (45.9) | 0.665 |
| Insomnia | 37 (36.6) | 89 (29.6) | 0.230 | 24 (34.8) | 59 (26.6) | 0.244 |
| Hypertension | 11 (10.9) | 25 (8.3) | 0.558 | 9 (13.0) | 20 (9.0) | 0.455 |
| Age at headache onset (years) | 29.9 (15.5) | 23.3 (13.5) | **< 0.001** | 30.6 (16.3) | 23.9 (14.2) | **0.003** |
| Duration of headache (years) | 12.4 (14.2) | 13.4 (12.3) | 0.486 | 13.9 (15.2) | 13.6 (12.4) | 0.892 |
| Headache attacks [19] | | | | | | |
| >4 h | 79 (78.2) | 257 (85.4) | 0.127 | 54 (78.3) | 192 (86.5) | 0.144 |
| <4 h | 22 (21.8) | 44 (14.6) | | 15 (21.7) | 30 (13.5) | |
| Headache days/month | | | 0.356 | | | 0.382 |
| ≥15 | 63 (62.4) | 170 (56.5) | | 35 (50.7) | 128 (57.7) | |
| <15 | 38 (37.6) | 131 (43.5) | | 34 (49.3) | 94 (42.3) | |
| Mean HIT-6 | 62.9 (6.5) | 64.4 (5.9) | **0.032** | 62.6 (7.2) | 64.0 (5.8) | 0.096 |
| Mean VAS | 6.5 (2.4) | 7.2 (2.1) | **0.007** | 6.5 (2.4) | 7.1 (2.0) | **0.034** |
| Migraineur | 69 (68.3) | 245 (81.4) | **0.009** | 48 (69.6) | 176 (79.3) | 0.131 |

Data are presented as mean (SD) or number (%). Significant values are presented in bold ($P < 0.05$). BMI, body mass index; HIT-6, Headache Impact Test-6 [18]; VAS, visual analogue pain scale (0 = no pain, 10 = worst possible pain) [15].

education, participants with college/university education were more satisfied with communication ($P = 0.047$), were older ($P < 0.001$), had a longer history of headaches ($P < 0.001$), had a longer consultation ($P < 0.001$), recalled the diagnosis more frequently ($P = 0.013$) and visited their GP more often in the wake of the consultation ($P < 0.001$). There were no statistical differences in patients' overall satisfaction with consultation, information, diagnosis, advice and prescriptions.

## Discussion

By comparing two different forms of consultation in a randomized manner and with similar group settings, we found that telemedicine was not inferior to a traditional specialist visit in terms of long-term satisfaction. When comparing the two groups, there was no difference in either satisfaction with consultation, communication, information, diagnostics and treatment or further GP treatment and follow-up at 12 months.

Recent published studies show that patients with neurological disorders and pain conditions are highly satisfied with telemedicine [20,21]. Conversely, headache sufferers are less satisfied with their healthcare [22]. This may be due to poor access to headache specialists [22] or misdiagnoses and suboptimal treatment [9]. However, centralizing headache care may diminish local GP follow-up, thus having a negative rebound effect on the quality of primary care [23]. At 12 months, the influence of headache on daily life was still high in both groups in our study (Table 3). The relatively high ongoing headache burden in these patients may reflect limited access to headache specialists and follow-up.

Constant improvements in information and communication technology, such as electronic patient records, electronic prescriptions and telemedicine, may give rise to more convenient healthcare with easier access to secondary neurological departments and headache specialists. Other advantages would be saving of travel time and cost, as well as possible shorter specialist consultations [2], without compromising the patient–doctor relationship [11]. Although we did not find any video deficit effects in the patient–doctor relationship, an important question that is in dispute and must be settled is how telemedicine consultations will affect the quality of care.

**Table 3** Satisfaction and headache characteristics among study participants 12 months after a specialist headache consultation

|  | Telemedicine $n$ (% PP/ITT) | Traditional $n$ (% PP/ITT) | $P$-value PP | $P$-value ITT |
|---|---|---|---|---|
| Overall satisfaction | 134 (88.7/67.0) | 127 (90.7/62.9) | 0.719 | 0.327 |
| Females | 107 (89.9/72.3) | 92 (89.3/60.1) | 1.000 | **0.036** |
| All migraineurs | 105 (90.5/67.3) | 98 (90.7/62.0) | 1.000 | 0.500 |
| Rural patients | 96 (88.1/65.8) | 88 (91.7/60.3) | 0.538 | 0.175 |
| Urban patients | 38 (90.5/70.4) | 39 (88.6/69.6) | 1.000 | 0.957 |
| Satisfied with |  |  |  |  |
| Communication | 139 (92.7/69.5) | 118 (86.1/58.4) | 0.106 | 0.055 |
| Information | 133 (88.1/66.5) | 119 (85.6/58.9) | 0.654 | 0.269 |
| Diagnosis | 118 (79.7/59.0) | 111 (79.9/55.0) | 1.000 | 0.516 |
| Advice | 115 (77.7/57.5) | 105 (76.6/52.0) | 0.943 | 0.386 |
| Prescriptions | 80 (58.0/40.0) | 70 (55.1/34.7) | 0.731 | 0.387 |
| Prefers traditional over TM | 48 (32.7/24.0) | 96 (69.6/47.5) | **0.001** | **0.001** |
| Overall satisfied with GP | 73 (50.0/36.5) | 72 (53.7/35.6) | 0.614 | 0.287 |
| College/university education | 53 (94.6/73.6) | 52 (92.9/65.0) | 1.000 | 0.513 |
| Primary/high school education | 81 (85.3/63.3) | 75 (89.3/61.5) | 0.563 | 0.466 |
| Females satisfied with |  |  |  |  |
| Communication | 112 (94.1/75.7) | 84 (84.0/54.9) | **0.027** | **0.001** |
| Information | 105 (88.2/70.9) | 87 (85.3/56.9) | 0.656 | **0.021** |
| Diagnosis | 93 (78.8/62.8) | 83 (81.4/54.2) | 0.761 | **0.034** |
| Advice | 89 (76.7/60.1) | 72 (71.3/47.1) | 0.449 | **0.038** |
| Prescriptions | 62 (57.4/41.9) | 50 (54.9/32.7) | 0.837 | **0.044** |
| Headache characteristics at 1 year |  |  |  |  |
| MID in HIT-6 from baseline | 66 (44.3) | 73 (52.9) | 0.181 |  |
| MID in VAS from baseline | 70 (47.9) | 56 (41.8) | 0.361 |  |

Data are presented as mean (SD) or number (%). Significant values are presented in bold ($P < 0.05$). ITT, intention-to-treat analysis; PP, per-protocol analysis. Pre-specified variable: Overall satisfaction. The other variables are non-pre-specified: GP, general practitioner; MID HIT-6, minimal clinical improvement in Headache Impact Test-6 (2.3) [14]; MID VAS, minimal clinical improvement in visual analogue pain scale (1.3 mm) (0 = no pain, 10 = worst possible pain) [15]; TM, telemedicine.

**Table 4** Non-pre-specified consultation preference of headache patients who underwent telemedicine evaluated 12 months after the consultation

|  | Preferred consultation Indifferent (n = 99)[a] | Traditional (n = 48) | P-value |
|---|---|---|---|
| Female | 77 (77.8) | 39 (81.3) | 0.788 |
| Mean age (years) | 37.5 (13.1) | 34.3 (13.5) | 0.172 |
| Level of education |  |  |  |
|   College/university | 41 (41.4) | 14 (29.2) | 0.209 |
|   Primary/high school | 58 (58.6) | 34 (70.8) |  |
| Education (years) | 13.8 (3.0) | 12.9 (2.7) | 0.057 |
| Waiting time (days) | 61.1 (30.4) | 68.8 (27.7) | 0.140 |
| Consultation time (min) | 39.4 (9.8) | 39.8 (9.2) | 0.810 |
| Rural patients | 72 (72.7) | 33 (68.8) | 0.760 |
| Urban patients | 27 (27.3) | 15 (31.3) | 0.760 |
| Overall satisfied with |  |  |  |
|   Consultation | 97 (98.0) | 35 (72.9) | **< 0.001** |
|   Communication | 96 (97.0) | 41 (87.2) | 0.055 |
|   Information | 94 (94.9) | 37 (77.1) | **0.003** |
|   Diagnosis | 89 (90.8) | 27 (57.4) | **< 0.001** |
|   Advice | 85 (85.9) | 28 (60.9) | **0.002** |
|   Prescriptions | 58 (65.9) | 20 (42.6) | **0.015** |
| Migraine | 78 (78.8) | 34 (70.8) | 0.392 |
| MOH | 18 (18.2) | 17 (35.4) | **0.036** |
| Headache attacks ≥4 h [19] | 81 (81.8) | 39 (81.3) | 1.000 |
| Headache days/ month ≥15 [19] | 37 (37.4) | 27 (57.4) | **0.035** |
| VAS at baseline | 7.0 (2.2) | 6.9 (2.3) | 0.692 |
| VAS at 12 months | 4.9 (2.8) | 5.7 (2.6) | 0.098 |
| HIT-6 at baseline | 63.6 (5.8) | 63.8 (7.6) | 0.888 |
| HIT-6 at 12 months | 59.3 (8.7) | 61.7 (9.8) | 0.142 |

Data are presented as mean (SD) or number (%). Significant values are presented in bold (P < 0.05). HIT-6, Headache Impact Test-6 [18]; MOH, medication overuse headache; VAS, visual analogue pain scale (0 = no pain, 10 = worst possible pain) [15]. [a]11 patients (7.5%) preferred telemedicine over traditional visits, 88 (59.9%) had no preference and 48 (32.7%) preferred traditional face-to-face visits.

Logically, patients who had undergone telemedicine were more indifferent to the type of consultation than those without such experience. Analysis of the telemedicine group showed that those who were indifferent to the form of consultation were more satisfied than patients who preferred a traditional consultation. The fact that patients who preferred traditional consultations in the telemedicine group had more headache days with more frequent medication overuse headache (MOH) indicate that traditional consultations are more suitable for patients with MOH. GPs have great potential to diagnose and treat the majority of patients with MOH, and could serve as a bridge to close this gap [24,25]. However, patients who had a consultation via telemedicine had not experienced a traditional specialist visit, which may have biased the results.

A high telemedicine acceptance rate [2] combined with a high telemedicine satisfaction frequency at both 3 months [11] and 12 months provide evidence for a positive attitude towards telemedicine among headache patients. Moreover, a high inclusion rate in the study from the referred headache patient population strengthens the external validity. The fact that patients accepted telemedicine and trial participation on beforehand, and most were satisfied with the audio and video communication [2], may have had an influence on the high proportion of satisfied patients. However, most of the eligible headache patients accepted telemedicine [2], indicating that the selection bias is of minor concern. Having consultations in a very structured manner could be another bias, but the findings of high satisfaction correspond to results of many other telemedicine studies [20,21,26]. An issue that needs further investigation is whether implementing telemedicine can reduce waiting times to access headache specialists and, at the same time, lessen deterioration of the headache burden.

Another finding in the present study was that patients with higher education were more satisfied with the communication at the specialist consultation. This may have been influenced by longer consultations and more GP follow-ups. However, the level of education showed no difference in satisfaction between the randomized groups. This finding is not in accordance with previous literature, which indicates that higher education is positively associated with the use of eHealth technology [27,28].

A surprising finding was that women seemed to be more satisfied with telemedicine in many categories of satisfaction. An explanation is that higher headache burden, and possibly younger age with higher education among the females, could have influenced this result. Based on these findings and results from two previous articles [2,11], a typical patient benefitting from telemedicine would be a young, well-educated rural woman who presents with a severe headache, similar to the older patient in the Introduction [1]. Because of many univariate analyses, these findings may be due to chance alone.

One advantage of this study is that participants were consecutively recruited from referrals to a secondary neurological outpatient department. Another advantage is that we included 72.2% of those that were screened for study participation (Fig. 1). However, as those who were older than 65 years of age were excluded, elderly patients with headache were not represented. A preponderance of primary headaches among women is in accordance with the literature [29,30], especially migraine, which affects women three times more often than men [30,31]. The larger

subgroup of women makes the analyses in this study more robust. Both groups in our study had similar reduction in headache burden. Thus, clinical improvement as a confounder of satisfaction is unlikely. In-hospital visits provide identical group conditions, but make this study less comparable to clinical practice. As we covered different aspects of satisfaction, the questionnaire content is valid, but we did not compare questions with a standardized questionnaire or rating scale. Cronbach's alpha shows that the different questionnaire aspects of satisfaction are reliable. Although the overall frequency of satisfied patients is similar to our 3-month results [11], there may be some recall bias after 12 months. Lack of a placebo group and blinding are two other weaknesses, but would be difficult to implement in this study. In addition to a high response rate, both per-protocol and ITT analyses of satisfaction frequency and different categories of satisfaction did not favour traditional visits over telemedicine.

Satisfaction with telemedicine consultations among non-acute headache patients is not inferior to traditional visits. These findings may stimulate more convenient and accessible headache care for patients, especially those in areas with no or limited neurological service.

## Acknowledgements

## Disclosure of conflicts of interest

The authors declare no financial or other conflicts of interest.

## Supporting Information

Additional Supporting Information may be found in the online version of this article:

**Figure S1.** The Department of Neurology at the University Hospital of North Norway is located at 69°N in the city of Tromsø (red dot). Inserted in the figure is the archipelago of Svalbard (2180 norwegian inhabitants, total area: 61022 km$^2$).
**Table S1.** Baseline demographics and clinical characteristics of patients who answered the 3-month questionnaire versus those who did not respond at 3 months.
**Table S2.** Baseline demographics and clinical characteristics of patients who answered the 12-month ques-

tionnaire versus those who did not respond at 12 months.
**Table S3.** Baseline demographics and clinical characteristics of the randomized groups in patients referred to specialist for headache (patients who did not answer the 3-month questionnaire).
**Table S4.** Baseline demographics and clinical characteristics of the randomized groups in patients referred to specialist for headache (patients who did not answer the 12-month questionnaire).

## References

1. Müller KI, Bekkelund SI. Hemicrania continua changed to chronic paroxysmal hemicrania after treatment with cyclooxygenase-2 inhibitor. *Headache* 2011; **51:** 300–305.
2. Müller KI, Alstadhaug KB, Bekkelund SI. Acceptability, feasibility, and cost of telemedicine for nonacute headaches: a randomized study comparing video and traditional consultations. *J Med Internet Res* 2016; **18:** e140.
3. Wechsler LR, Tsao JW, Levine SR, *et al.* Teleneurology applications: report of the Telemedicine Work Group of the American Academy of Neurology. *Neurology* 2013; **80:** 670–676.
4. Craig J, Chua R, Wootton R, Patterson V. A pilot study of telemedicine for new neurological outpatient referrals. *J Telemed Telecare* 2000; **6:** 225–228.
5. Cottrell C, Drew J, Gibson J, *et al.* Feasibility assessment of telephone-administered behavioral treatment for adolescent migraine. *Headache* 2007; **47:** 1293–1302.
6. Yurkiewicz IR, Lappan CM, Neely ET, *et al.* Outcomes from a US military neurology and traumatic brain injury telemedicine program. *Neurology* 2012; **79:** 1237–1243.
7. Wechsler RL. Advantages and limitations of teleneurology. *JAMA Neurol* 2015; **72:** 349–354.
8. Rossi P, Faroni J, Tassorelli C, Nappi G. Diagnostic delay and suboptimal management in a referral population with hemicrania continua. *Headache* 2009; **49:** 227–234.
9. Lipton RB, Scher AI, Steiner TJ, *et al.* Patterns of health care utilization for migraine in England and in the United States. *Neurology* 2003; **60:** 441–448.
10. Klapper JA, Klapper A, Voss T. The misdiagnosis of cluster headache: a nonclinic, population-based, Internet survey. *Headache* 2000; **40:** 730–735.
11. Müller KI, Alstadhaug KB, Bekkelund SI. Telemedicine in the management of non-acute headaches: a prospective, open-labelled non-inferiority, randomised clinical trial. *Cephalalgia* 2016; doi: 10.1177/0333102416654885. [Epub ahead of print].
12. Questback. https://www.questback.com/ (accessed 18/04/2016). Archived by WebCite at https://www.webcitation.org/6gr3li1zf.
13. Sealed Envelope Ltd 2012. Power calculator for binary outcome non-inferiority trial. https://www.sealedenvelope.com/power/binary-noninferior (accessed 12/04/2016). Archived by WebCite at https://www.webcitation.org/6giIBoM6x.
14. Coeytaux RR, Kaufman JS, Chao R, Mann JD, Devellis RF. Four methods of estimating the minimal important difference score were compared to establish a

clinically significant change in Headache Impact Test. *J Clin Epidemiol* 2006; **59:** 374–380.

15. Lundqvist C, Benth JS, Grande RB, *et al*. A vertical VAS is a valid instrument for monitoring headache pain intensity. *Cephalalgia* 2009; **29:** 1034–1041.

16. World Medical Association 2008. World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. https://www.wma.net/en/30publications/10policies/b3/index.html (accessed 18/05/2016). Archived by WebCite at http://www.webcitation.org/6hb61FDlz.

17. The Norwegian Research and Management database (FAS). https://forskningsprosjekter.ihelse.net/prosjekt/HST959-10 (accessed 12/04/2016). Archived by WebCite at http://www.webcitation.org/6giJSsbSY.

18. Kosinski M, Bayliss MS, Bjorner JB, *et al*. A six-item short-form survey for measuring headache impact: the HIT-6. *Qual Life Res* 2003; **12:** 963–974.

19. Lipton RB, Bigal ME, Steiner TJ, Silberstein SD, Olesen J. Classification of primary headaches. *Neurology* 2004; **63:** 427–435.

20. Davis LE, Coleman J, Harnar J, King MK. Teleneurology: successful delivery of chronic neurologic care to 354 patients living remotely in a rural state. *Telemed J E Health* 2014; **20:** 473–477.

21. Hanna GM, Fishman I, Edwards DA, *et al*. Development and patient satisfaction of a new telemedicine service for pain management at Massachusetts General Hospital to the Island of Martha's Vineyard. *Pain Med* 2016; **17:** 1658–1663.

22. Tassorelli C, Farm I, Kettinen H, *et al*. Access to care – an unmet need in headache management? *J Headache Pain* 2014; **15:** 20.

23. Nicolini D. The work to make telemedicine work: a social and articulative view. *Soc Sci Med* 2006; **62:** 2754–2767.

24. Kristoffersen ES, Straand J, Vetvik KG, *et al*. Brief intervention by general practitioners for medication-overuse headache, follow-up after 6 months: a pragmatic cluster-randomised controlled trial. *J Neurol* 2016; **263:** 344–353.

25. Frich JC, Kristoffersen ES, Lundqvist C. GPs' experiences with brief intervention for medication-overuse headache: a qualitative study in general practice. *Br J Gen Pract* 2014; **64:** e525–e531.

26. Gustke SSBD, West VL, Rogers LO. Patient satisfaction with telemedicine. *Telemed J* 2000; **6:** 5–13.

27. Amo L. Education-based gaps in eHealth: a weighted logistic regression approach. *J Med Internet Res* 2016; **18:** e267.

28. Kontos E, Blake KD, Chou WY, Prestin A. Predictors of eHealth usage: insights on the digital divide from the Health Information National Trends Survey 2012. *J Med Internet Res* 2014; **16:** e172.

29. Rasmussen BK, Jensen R, Schroll M, Olesen J. Epidemiology of headache in a general population – a prevalence study. *J Clin Epidemiol* 1991; **44:** 1147–1157.

30. Global Burden of Disease Study 2015. In: Institute for Health Metrics and Evaluation (IHME) S, WA, USA. http://ghdx.healthdata.org/gbd-results-tool?params=querytool-permalink/1e1e0e0f14ead39cf9d234147f456129 (accessed 21/11/2016)

31. Vetvik KG, MacGregor EA. Sex differences in the epidemiology, clinical features, and pathophysiology of migraine. *Lancet Neurol* 2016; **16:** 76–87.