Research Square

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Effect of video consultation for non-acute headache by neurologist on consultation rate in general practice during one-year follow-up. Randomized controlled trial

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Research Article

Keywords: Primary health care, Headache, Referral, Video consultation, Telemedicine, Ehealth, Randomized controlled trial, RCT

Posted Date: September 21st, 2023

DOI: https://doi.org/10.21203/rs.3.rs-3337473/v1

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Abstract

Background

Patient´s access to headache specialists varies in the population. Video consultations may help, but the effect of using communication technology on headache management in the population is incompletely understood. This study determined whether use of video consultations for non-acute headache patients at specialist were noninferior to face-to-face consultations in the need for subsequent headache visits in general practice at follow-up.

Methods

Four hundred and two non-acute headache patients consecutively referred to neurologist from general practitioners in North Norway were included in a randomized controlled noninferiority trial. Frequency of patients consulting general practitioner for headache and median number of headache consultations 0–12 months after specialist consultation were compared between groups initially consulted by video or face-to-face consultations.

Results

Ninety-two (60.9%) of the patients in the video group and 93 (66.4%) in the face-to-face group consulted general practitioners for headache problems during the follow-up period, $p = 0.274$. The median (IQR range) number of consultations were 1 (IQR: 0–14) (video) and 1 (IQR: 0–15) (face-to-face), $p = 0.154$. Clinical characteristics including, headache impact, pain score and patients satisfied with headache information, communication, headache advice, diagnostic information, and headache medication at GP during follow-up were similar between the two groups.

Conclusion

Treating headache patients by using video consultations at neurologist did not result in higher consultation rate at follow-up in general practice. These data support use of video as a useful method in the treatment of headache at specialist in terms of organization of headache management in the population.

Trial registration:

Trial registration number NCT02270177. Registration date: October 2, 2014

Background

Headaches are common complaints in the population and a frequent reason for people to seek healthcare [10, 14]. Although headache is mild and transient in many cases, it may be burdensome and transform to chronic headache and coincide with different health problems such as pain syndromes [26], psychiatric symptoms [15] and impaired work performance with increased costs to patients and society [20]. Migraine is estimated as the third most burdensome neurological disorder after stroke and Alzheimer ´s disease [9].

Reports over time show that headache syndromes are underdiagnosed and undertreated in many cases [8, 18]. Variable access to headache specialists across countries emphasizes the need for more knowledge about alternative and easier consultation forms like use of video or other electronic devices in clinical practice [27]. Additionally, a shared consultation practice between specialist services and general practitioners available to the patients for optimal headache care is not always provided and needs to be better coordinated [16, 25]. Thus, telehealth research for headache has grown [3, 29]. Neither treatment outcome, safety nor patient satisfaction with telehealth were inferior to traditional consultation for headache patients seeing a neurological specialist [3, 23]. Also, patients with difficult headache may benefit from telemedicine [7, 11]. However, the literature lacks randomized studies investigating how remote headache consultations at specialist affect subsequent consultation activity in general praxis.

The aim of this study was to test the hypothesis that video consultation for new non-acute headache patients referred to an outpatient neurological clinic is not inferior to traditional face-to-face consultations as far as need for subsequent follow-up consultations in general practice.

Materials and methods

Study design and recruitment

The present study is an open label randomized, noninferiority clinical trial (ClinicalTrials.gov; id. NCT02270177). Headache patients (n = 402) consecutively referred from general practitioners (GPs) to a neurological outpatient clinic during a 2.5-year period (30th September 2012 until 30th March 2015) were identified, screened, assigned to either video- or face-to-face consultations, and then consulted by a neurologist (Fig. 1).

Randomization and sample

Figure 1 shows a flow chart of eligible patients, dropouts, and reasons for dropout. Selection criteria were: 1) Patients referred from GPs to neurologist for headache, 2) no evidence of secondary headache i.e., headaches classified as primary headache without specific causes [1] except patients with suspected medication overuse headache, 3) Norwegian speaking men and women aged 16–65 years, 4) no previous consultation by neurologist for headache during the past two years, 5) waiting time from referral to consultation ≤ 4 months.

At entrance of the Neurological Department, the Tromsø University Hospital, a study nurse welcomed the patients, controlled the self-administered prefilled forms and consents, and called upon the randomization administrator (Centre for Quality Improvement and Development at the hospital). After being block-randomized, they were guided to the examination room for face-to-face consultations or to the videoconference room. Video consultations were performed by using a video conference system: Cisco C40 Integrator package, Multisite and Touch-Control Device for C Series; Cisco, San Jose, California, USA, Cisco Precision HD 1080p 12x camera. Further, a NEC X551s 55"LED monitor, audio-technica ceiling microphones and JBL LSR2325P active speakers, integrator Package C40 Dual Display option and a Cisco Touch-Control Device for C Series. This equipment connected to Cisco EX60 unit with an in-touch panel at the neurologist's office provided a direct two-way video- and audio communication. Video consultations and face-to-face consultations were performed at the same place. The study nurse confirmed that the web-camera and microphone worked well and were operated correctly by the patients. A short training to assure optimal communication with the specialist was provided before the consultations started. A standardized interview developed before the trial was used during the consultations along with check lists for inclusion criteria and diagnostic classification. The non-inferiority margin was defined by < 15% impairment in outcome measures in the video-group compared to the face-to-face group. Sample size estimation and further details are published elsewhere [22].

Data Collection and Endpoints

Demographic, social, clinical and endpoint data were obtained by self-administered prefilled forms and structured interview at baseline and by questionnaire at one-year follow-up. The prefilled forms included Headache Impact Test-6 (HIT-6) measuring 6 headache impact items (pain, social-, role- and cognitive functioning, vitality, and psychological distress). Every question was answered by "Never, Rarely, Sometimes, Very Often or Always", and each answer scored respectively 6, 8, 10, 11 or 13 points [30]. Pain intensity score using a horizontal visual analogue scale (VAS) ranging from 0 to 10 (0 = no pain, 10 = worst possible pain) was prefilled by the patients [19]. Clinical and headache characteristics and diagnosis according to International Classification of Headache Disorders-2 (ICHD-2) [1] were assessed [22]. At 12-months follow-up, a questionnaire addressing demographics, clinical and headache characteristics and endpoint variables was sent to the patients either through an online survey service (Questback) or by a postal letter. Non-responders received a reminder two weeks later. Primary endpoints were recorded from the patients' registration form as follows: "Have you consulted your GP for headache after the specialist consultation?" ("Yes" or "No"), and "number of headache consultations at GP after the specialist consultation". Further questions included: "Where you satisfied with the follow-up consultation(s) at GP? ("Yes" or "No"). Also, neurological consultations for headache during follow-up, medication; painkillers, triptans, and preventive headache drugs used in the last month, chronic neck pain; continuously presence of neck pain during the last three months, insomnia (DSM-IV criteria) were some of the recorded clinical characteristics.

Statistical Analyses

Descriptive variables are presented as mean and standard deviation (SD) or median and interquartile range (IQR) in variables with skewed distribution as observed for number of GP and neurological consultations during follow-up. Consequently, comparisons of endpoints defined by continuous data between the two randomized groups were performed by two-sided independent Student t-test respectively Mann Whitney U-test. Categorical variables were presented as numbers and % while data used for group comparisons were analyzed by Chi-Square Test. Level of statistical significance was set at $p < 0.05$. Data were analyzed with SPSS (version 27, IBM Corp).

Results

One-year response-rates after neurological specialist consultation were 151/200 (75.5%) in the video-group and 140/202 (69.3%) in the face-to-face group, $p = 0.119$ (Table 1). Mean values and group comparisons of patient´s characteristics at baseline and one-year follow-up are presented in Table 1. A majority had migraine as primary headache and there were not found statistically differences in any dimension being compared between the two groups (Table 1). Medical treatment was initiated in about 4/5 of the patients in any group during the specialist consultation, most commonly Triptans (Table 2). There were no differences in any headache-related drug prescriptions (Table 2).

Table 1
Clinical characteristics in randomized groups of patients referred to specialist for headache consulted by video or face-to-face. Baseline and 12-month follow-up data are presented with mean (SD) or numbers (%)

	Baseline			**12-month follow-up**		
	Video (n = 200)	Face-to-face (n = 202)	*P*-value	Video (n = 151)	Face-to-face (n = 140)	*P*-value
One-year response, n (%)				152/200 (76.0)	139/202 (68.8)	0.119
Females, n (%)	151 (74.8)	151 (74.8)	1.0	117 (77.5)	105 (75.0)	0.784
Age, years	37.6 (13.0)	38.0 (13.4)	0.339	38.1 (13.8)	37.8 (13.7)	0.849
Education, years	13.7 (2.9)	13.7 (2.9)	0.699	13.7 (2.9)	13.5 (3.1)	0.596
Sick leave due to headache, n (%)	60 (30.0)	60 (29.7)	1.0	40 (26.5)	42 (30.0)	0.515
Waiting time to specialist from baseline, days	61.8 (27.5)	62.3 (28.7)	0.855	61.9 (27.4)	61.1 (29.2)	0.811
Consultation duration, minutes	41.7 (12.0)	40.8 (10.5)	0.401	41.4 (10.5)	41.46 (10.7)	0.954
Obesity, BMI ≥ 30, n (%)	51 (25.5)	50 (24.8)	0.909	40 (26.5)	41 (29.3)	0.601
Chronic neck pain, n (%)	57 (28.5)	56 (27.7)	0.912	65 (43.0)	66 (47.1)	0.479
Insomnia, n (%)	59 (29.5)	67 (33.2)	0.453	42 (27.8)	41 (29.3)	0.795
Hypertension, n (%)	19 (9.5)	17 (8.4)	0.730	15 (9.9)	14 (10.0)	1.0
Abbreviations: BMI, body mass index						

Table 2
Headache characteristics and treatment in randomized groups of patients referred to specialist for headache consulted by video or face-to-face. Baseline and 12-month follow-up data are presented with mean (SD) or numbers (%)

	Baseline			**12-month follow-up**		
	Video (n = 200)	Face-to-face (n = 202)	*P*-value	Video (n = 151)	Face-to-face (n = 140)	*P*-value
Onset of headache, age	25.0 (15.1)	24.8 (13.5)	0.893	25.5 (15.4)	25.5 (14.5)	0.990
Headache duration, years	13.9 (13.0)	12.4 (12.6)	0.222	13.9 (12.7)	13.5 (13.5)	0.775
HIT-6	64.4 (6.4)	63.7 (5.8)	0.276	64.1 (6.3)	63.3 (6.1)	0.285
VAS	7.04 (2.2)	6.99 (2.2)	0.819	7.09 (2.1)	6.86 (2.2)	0.363
Headache subtype [a]						
Migraine	106 (53.0)	13 (55.9)	0.624	79 (52.3)	77 (55.0)	0.734
Tension-type	15 (7.5)	8 (4.0)	0.198	12 (8.0)	5 (3.6)	0.182
Medication overuse headache	35 (17.5)	38 (18.8)	0.835	27 (17.9)	26 (18.6)	1.0
TAC [b]	16 (8.0)	16 (7.9)	1.0	17 (11.3)	11 (7.9)	1.0
Drugs prescribed	169 (84.5)	161 (79.7)	0.242	128 (84.8)	108 (77.1)	0.178
Triptans	75 (37.5)	81 (40.1)	0.610	59 (39.1)	53 (37.9)	1.0
NSAIDs	53 (26.5)	56 (27.7)	0.823	43 (28.5)	34 (24.3)	0.507
Antihypertensive	33 (16.5)	33 (16.3)	1.0	24 (15.9)	23 (16.4)	0.875
Antiepileptic	26 (13.0)	25 (12.4)	0.882	20 (13.3)	17 (12.1)	0.861
Antidepressant	58 (29.0)	42 (20.8)	0.065	41 (27.2)	27 (19.3)	0.165

Abbreviations: BMI, body mass index; HIT-6, Headache Impact Test-6; NSAID, Non-Steroidal Anti-Inflammatory Drugs; VAS, visual analogue scale

[a] Most prominent headache subtype given by specialist; [b] TAC, trigeminal autonomic cephalalgias (cluster headache, paroxysmal hemicrania and hemicrania continua)

	Baseline			12-month follow-up		
Patients satisfied with specialist consultation	164 (82.0)	150 (74.3)	0.200	132 (87.4)	123 (87.9)	1.0
Abbreviations: BMI, body mass index; HIT-6, Headache Impact Test-6; NSAID, Non-Steroidal Anti-Inflammatory Drugs; VAS, visual analogue scale						
[a] Most prominent headache subtype given by specialist; [b] TAC, trigeminal autonomic cephalalgias (cluster headache, paroxysmal hemicrania and hemicrania continua)						

GP consultations (numbers/frequencies of patients and median numbers of consultations) and patient satisfaction with consultations are presented in Table 3. More than 60% of the video consultations at neurologist resulted in additional contact in primary care at follow-up regardless of consultation form. A slightly higher frequency of patients treated face-to-face reported that they had consulted GP for headache in the follow-up period and they also tended to be more satisfied with the consultation, although not statistically significant (Table 3). Thus, less than 40% of the patients in any group were satisfied with the GP consultations for headache during follow-up (Table 3). Nor were there any differences between the groups in follow-up consultation rates for headache at neurologist; 20 (13.3%) in the video group and 21 (15.0%) in the face-to-face group consulted neurologist for headache during one-year follow-up, $p = 1.0$.

Table 3
One-year follow-up consultations at general practitioner in patients randomized to either video- or face-to-face consultations for headache by neurologist. Numbers (%) are presented

	Video (n = 151)	Face-to-face (n = 140)	*P* - value
GP consultation for headache	92 (60.9)	93 (66.4)	0.274
GP consultations, median (IQR range)	1.0 (0–14)	1.0 (0–15)	0.154
Patients satisfied with follow-up at GP	47 (31.1)	54 (38.6)	0.386
Satisfied with headache information	54 (35.8)	52 (37.1)	1.0
Satisfied with communication	74 (49.0)	72 (51.4)	0.866
Satisfied with headache advice	44 (29.1)	46 (32.9)	0.772
Satisfied with diagnostic information	52 (34.4)	56 (40.0)	0.375
Satisfied with headache medication	35 (23.2)	45 (32.1)	0.177
Abbreviation: GP General practitioner.			

Discussion

The results from this study showed that the need for follow-up visits in general practice after consulting a neurological specialist for headache was similar between groups of patients randomized to video- and face-to-face consultations. Hence, about 60% of the patients visited GP´s for follow-up within one year for headache problems. Use of video consultations for headache by specialist may be seen as a good alternative in terms of organization of headache treatment in the population.

Patients with neurological disorders including headache and other pain conditions are well treated with telemedicine [2, 5, 13]. Also from a specialist point of view, headache and follow-up consultations were reported to be well suited for telemedicine [17]. A multicenter RCT study found diagnostic accuracy to be favorable in 212 migraine patients via an online system [4]. Furthermore, RCT-studies have recently demonstrated good outcome for patients with headache treated via telemedicine at specialist [3]. This include dimensions such as treatment efficacy, patient satisfaction, safety, and feasibility, but there has so far been little focus on headache management in general practice after specialist consultation. A secondary analysis of a RCT-study in new neurological referred outpatients showed that patients consulted by telemedicine (n = 86) had non-significantly more often a neurological review appointment than those consulted face-to-face (n = 82) (29% vs. 22%) [2]. Although this study included a heterogenic group of neurologic patients with a different outcome measure, this finding conforms with the present one in respect to follow-up activity since follow-up consultation rates at GP and neurologist were similar between the two study groups.

Although the two study groups in the present study were equal in many aspects, less than 40% were satisfied with follow-up consultations in general practice in any group. Reasons for that are not answered in the present study and is from the literature incompletely understood. Misdiagnosis, undertreatment and variable access to headache specialists are reported findings to consider, however [18, 27]. Thus, rural areas being less supported by specialist services may motivate use of digital health technology as an alternative consultation form [28]. The best headache care in 10 European countries was graded as followed: treatment at specialist > treatment by GP > self-medication [16]. This corresponds with the present findings and may indicate need for better education. Furthermore, variation in referral practice from GP´s to specialist in relation to availability to specialist for headache patients, and effect of patient behavior and GP management are largely unexplained and should be addressed [6, 21]. Hence, headache patients referred to specialist, consulted GP more often and were more concerned about their headache than the non-referred without necessarily having more serious headaches. Furthermore, negative expectations about headache consequences may influence upon the time course of the disease [12, 24]. Consequently, more RCT studies are needed.

Since this study compares different consultation forms and not specific treatment options, important RCT characteristics like placebo group and blinding are difficult to obtain. Use of questionnaire for endpoint assessment, lack of interim analyses comparing additional clinical information between the groups and limited follow-up period are other questionable aspects. Contrary, the RCT design and

consecutively inclusion of patients from general practice with few dropouts during the trial course are features that strengthen internal respectively external validity of the study. Also, the risk of response-bias is reduced by the RCT-design and the insignificant difference in one-year response between the groups. In-hospital consultations may provide similar group conditions but makes the study less comparable to clinical practice, however.

Conclusions

By comparing two groups of headache patients with similar social and clinical characteristics, the current study showed that use of video was not inferior to face-to-face consultations in respect to GP follow-up consultation rate. The findings support recommendation of video in consulting headache patients also for reasons of headache management. Thus, more studies preferably with RCT design aiming to identify patient groups suitable for eHealth consultations both at GP and specialist are needed.

Abbreviations

BMI
Body mass index
DSM
Diagnostic and Statistical Manual of Mental Disorders
GP
General practitioner
ICHD-2
International Classification of Headache Disorders-2
IQR
Interquartile range
HIT-6
Headache impact test-6
NA
Not applicable
NSAID
Non-Steroidal Anti-Inflammatory Drugs
RCT
Randomized controlled trial
REC
Regional ethical committee
TAC
Trigeminal autonomic cephalalgias
VAS
visual analogue scale.

Declarations

Acknowledgement

The author thanks the Department of Neurology, the University Hospital of Tromsø for skillful help with patient logistics and data collection.

Funding

The North Norway Health Authority funded the study.

Availability of data and materials

Data and materials for this study are available on request.

Authors' contributions

SIB designed the study, analyzed, and interpreted the data, drafted the article, revised it, and approved the final manuscript.

Ethical approval and consent to participate

The study was conducted in accordance with the Declaration of Helsinki. Oral and written informed consent were obtained from all participants before data collection. The Norwegian National Committee for Medical and Health Research Ethics (REC), number 2009/1430/REK approved the study. The study was registered at ClinicalTrials.gov (id. NCT02270177).

Consent for publication

Not applicable

Competing interests

Not applicable

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Figures

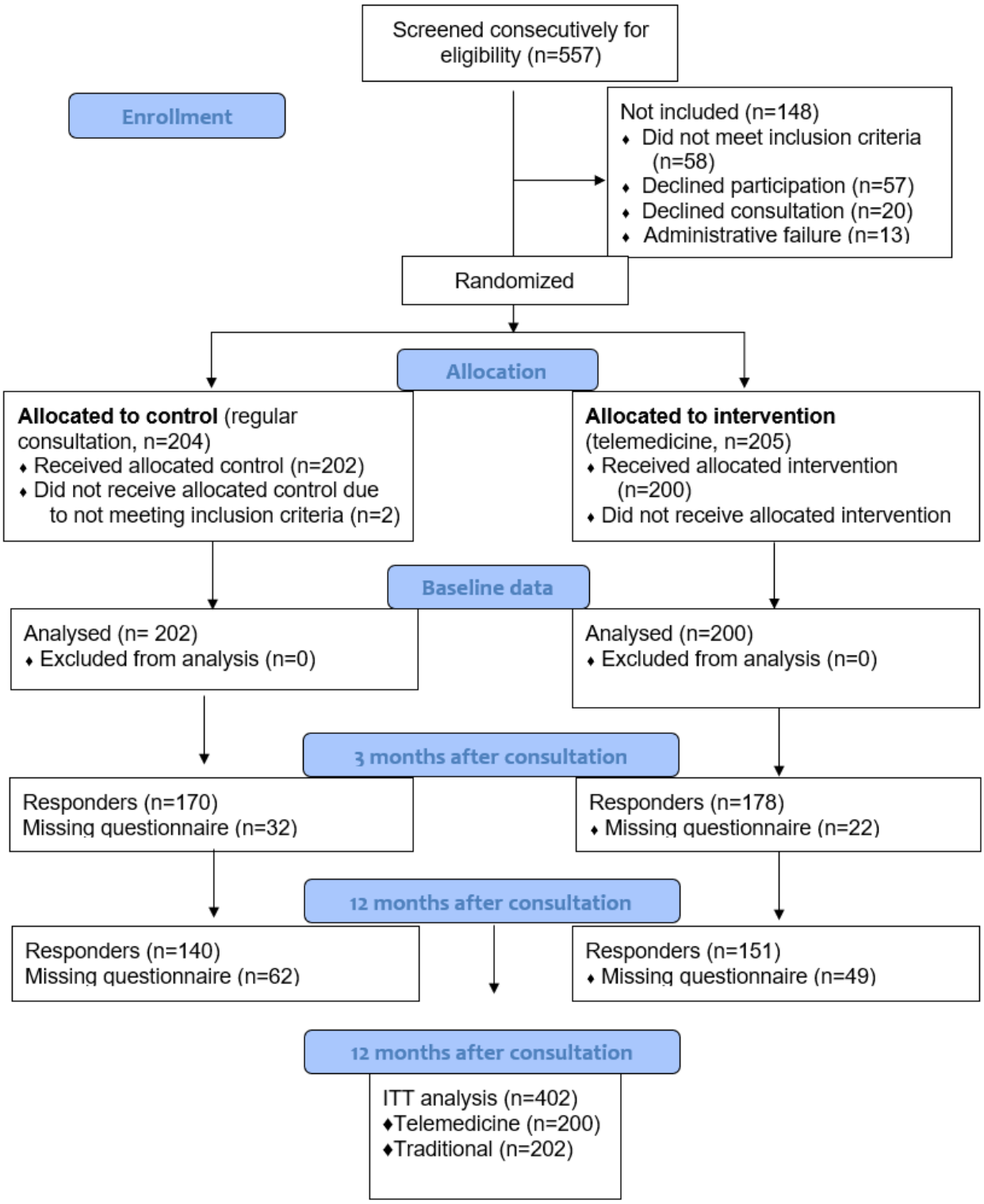


Figure 1

Flow chart of patients referred to neurologist from general practitioners for headache and randomized to video consultation or face-to-face consultation

Supplementary Files

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