ORIGINAL ARTICLE

Efficacy of emergency medical center use of a protocol during telephone calls to give medical advice related to fever or gastroenteritis: a cluster randomized controlled trial

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Objective. To determine the efficacy of emergency medical center physicians' use of a protocol to guide their management of telephone consultations for fever and gastroenteritis.

Methods. Cluster randomized controlled trial. Participating centers were randomized to use the telephone protocol or provide usual telephone assistance. Six emergency centers in France included calls from patients needing advice on fever or gastroenteritis. Centers assigned to the protocol followed specific guidelines on managing the call and giving advice on treatment. Primary endpoints were the number of in-person visits and hospital admissions required within 15 days of the call. Secondary endpoints were patient satisfaction and costs.

Results. A total of 2498 calls were included. Use of the assigned protocol while attending 1234 calls was associated with a relative risk for hospitalization or an unscheduled in-person visit for care of 0.70 (95% CI, 0.58–0.85) versus usual practice. Ambulance use, admission to an intensive care unit, mortality, morbidity, and symptom improvement did not differ significantly between centers using the protocol and those following usual practice. Ninety percent of the patients were satisfied. The cost of care was €91 in centers applying the protocol and €150 in the other centers (P < .01).

Conclusions. Use of the protocol was associated with fewer unscheduled in-person visits for care and fewer hospital admissions. The protocol is safe and less costly than the centers' usual approaches to giving telephone advice.

Keywords: Call center. Telephone consultation. Primary care. Cost-effectiveness. Satisfaction. Treatment adherence and compliance. Fever. Gastroenteritis.

Eficacia de un protocolo de asesoramiento médico telefónico formalizado para consultas por fiebre o gastroenteritis en centros de comunicación médica de emergencia. Ensayo clínico AMTF

Objetivos. Determinar la eficacia de un protocolo de asesoramiento médico telefónico formalizado (AMTF), realizado por un médico para consultas, para fiebre o gastroenteritis en centros de comunicación médica de emergencia.

Método. Ensayo clínico por conglomerado, controlado. Los pacientes fueron aleatorizados al grupo AMTF o al grupo de atención habitual. Participaron 6 centros de comunicación médica de emergencia franceses. Se incluyeron pacientes que solicitaban asistencia telefónica por fiebre o gastroenteritis. El grupo ATMF realizó recomendaciones protocolizadas sobre el manejo terapéutico. Se valoró el número de consultas presenciales o ingreso hospitalario durante los 15 días siguientes a la consulta. También se evaluó la satisfacción del paciente y el coste económico.

Resultados. Se incluyeron 2.498 llamadas. El grupo ATMF (n = 1.234) tuvo un riesgo relativo de 0,70 (CI 95% 0,58 a 0,85) de requerir un ingreso hospitalario o de realizar una consulta no programada durante el seguimiento. No hubo diferencias entre los dos grupos en cuanto al uso de ambulancia, el ingreso en cuidados intensivos, la mortalidad o morbilidad y la mejoría de los síntomas. La satisfacción de los pacientes fue del 90%. El coste total fue de 91 euros en el grupo de la ATMF y de 150 euros en el grupo de atención habitual (p < 0,01).

Conclusiones. El grupo ATMF se asoció con una disminución de las consultas presenciales no programadas o del ingreso en el hospital. Este procedimiento es seguro y comporta un menor coste que la atención que se realiza habitualmente en la actualidad.

Palabras clave: Centro de llamadas. Consulta telefónica. Atención primaria. Coste-efectividad. Satisfacción. Cumplimiento. Fiebre. Gastroenteritis.

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Introduction

Difficulty to access primary care (PC) services outside normal office hours is a frequent reason for patient dissatisfaction¹. For several years now, telephone consultations have been gaining in popularity². This type of consultation has been used mainly for out-ofhours consultations³. Nowadays, the possibility of telephone consultation is common and is integrated into patient-centered healthcare systems⁴. The response to the telephone consultation depends on the assessment made and may involve the dispatch of an ambulance, an emergency medical service (EMS) or medical advice. This last possibility has different modalities: recommendation to go to an emergency department (ED), consultation with a general practitioner out of hours, or other ways of managing the patient until he/ she can attend a face-to-face visit during regular office hours.

The effectiveness of telephone consultation has been assessed based on the decrease in the number of PC and ED visits. Other endpoints are patient satisfaction, associated costs and clinical outcomes. However, the benefits of telephone consultation in terms of safety, service use, cost and patient satisfaction are controversial^{2,3,5,6}. For instance, the impact of telephone consultations on PC or ED workload has been questioned. Some studies showed a higher rate of face-to-face consultations in PC or ED^{2,7,8}. In contrast to this finding, other studies found that telephone consultations were associated with lower cost and decreased workload in PC or ED visits^{6,9}.

In France, the need for after-hours assistance is centralized through the emergency medical communication centers (EMCC). France is divided into regions (13) and departments (100). Each department has its own EMCC. The performance of telephone medical advice is very variable, according to previous studies it represents between 5% and 66% of calls^{10,11}. The main pathologies for which telephone medical advice is given are fever and gastroenteritis symptoms^{12,13}.

Our hypothesis is that formalized telephone medical advice (FTMA), performed by a physician on patients calling after hours to EMCC for isolated fever or gastroenteritis symptoms, would reduce ED utilization or faceto-face consultation in PC compared to usual practice.

Method

Design

The methods and design of the study were described in detail in an earlier study¹⁴. In summary, this was a two-group, prospective, open-label, comparative, randomized, prospective clinical trial involving 6 EMCCs. Centers were randomized into two groups (1:1) according to the method of telephone management, either a formalized telephone medical advice offer (FTMA group) or usual medical care (control group). Out-of-hours was defined as the period between 8 p.m. and 7:59 a.m. on weekdays, between 1 p.m. and 8 a.m. on Saturdays, and 24 hours on Sundays and public holidays. In France, the management of out-of-hospital emergencies is the responsibility of the EMCC. All telephone inquiries are received by switchboard operators (available 24 hours a day) and can be referred to a physician.

Selection of participants

Patients over 1 year of age with fever, specified as a body temperature above 38.0°C, or with symptoms of gastroenteritis, defined as nausea, vomiting, or diarrhea, were included. Onset of symptoms had to be < 72 hours. The person making the call had to be \geq 18 years old. Exclusion criteria were three: pregnant patient, severity criteria (temperature above 41.0°C, impaired level of consciousness, rash, dyspnea, signs of dehydration, chest pain, neurologic symptoms, upper or lower gastrointestinal tract bleeding) or communication problems (noncommunicative patient, language barrier).

Intervention

The EMCC of the FTMA group always carried out telephone medical advice according to three protocolized sections. Firstly, the caller was reassured and the case was assessed; secondly, advice was given on patient management and treatment; thirdly, understanding of the measures to be taken was checked. In addition, therapeutic protocols were included, which could include telephone prescription. In fever consultations, it was recommended to change the patient's clothes when necessary, ventilate the room and offer frequent cold drinks. Likewise, antipyretic treatment with paracetamol or ibuprofen could be prescribed by telephone. In cases with symptoms of gastroenteritis, early rehydration by drinking small amounts of water at frequent and regular intervals was indicated. In children, oral rehydration solution (one sachet in 200 mL of water) was recommended. It was advised to start solid oral intake 46 hours after rehydration to reduce the frequency of diarrheal stools. Racecadotril (Tiorfan®) could be prescribed by telephone, three times a day and with the dose adjusted by weight. In cases of fever or pain, paracetamol was prescribed.

To ensure correct understanding of the instructions, the person who carried out the consultation had to repeat the recommendations received from the EMCC. In both cases of fever or gastroenteritis symptoms, it was indicated to repeat the call in case of persistence of fever, worsening of the symptomatology or appearance of new symptoms.

The EMCCs in the control group handled calls in the usual manner. The EMCC physician was free to give advice as he/she saw fit.

Measures

Inclusion was performed when the EMCC caller agreed to participate. The EMCC investigator completed the study information. Regardless of the assigned group, a clinical trial technician made the follow-up call 15 ± 4 days after the initial call. The patient was considered lost to follow-up if no response was obtained after 15 calls.

Outcome variables

The main outcome variable was a face-to-face consultation outside usual office hours with a PC physician, or a consultation in the ED, or requiring hospital admission, during the 2 weeks following the initial call. The reason for the consultation or hospital admission had to be the same as the reason for the initial call.

The secondary outcome variables were three. First, 15-day follow-up variables defined as: consultations in PC or the ED, prehospital medical service interventions, ambulance intervention, intensive care admission, all-cause mortality, morbidity, clinical outcome, number of recalls to the EMCC, need for sick leave and its duration. Secondly, patient or caregiver satisfaction, in cases where the patient was a minor. This was evaluated with a dichotomous question (yes/no) and a numerical scale (0: completely dissatisfied; 10: extremely satisfied). Thirdly, the cost of care and compliance with the medical advice received, as reported by the patient or the person responsible for the patient, were assessed.

In accordance with French law, oral patient consent was considered sufficient for participation in this clinical trial. All participants received a copy of the study information sheet. The study was approved by the Comite de Protection des Personnes Ile-de-France 10. Data management was approved by the Comité consultative sur le traitement de l'information en matière de recherché and by the Commission nationale informatique et liberté. The study is registered on ClinicalTrials.gov, number NCT02286245.

Statistical analysis

FTMA was considered to result in an absolute reduction of at least 10% in the intervention group and for each reason for consultation (fever or gastroenteritis). With this premise, and a power of 85%, an alpha risk of 5% and a loss to follow-up of 8%, the number of patients to be included was 2,880 patients, 1,440 in each group, 720 patients in each reason for consultation.

Inclusion was conducted for 16 months. At each center and for each indication, a random sample of 4 patients per week was obtained outside epidemic periods (about 42 weeks) and 8 patients per week during periods when an epidemic existed (about 10 weeks). On the computer-generated randomization list, 4 (or 8 during an epidemic) dates and times were indicated for

each week and for each study indication. The first patient whose call was closest to the selected dates and times was included.

Categorical variables are expressed as absolute number and percentage, continuous variables as median and interquartile range. The primary outcome variable was assessed using a generalized estimating equation model, and taking into account the cluster trial design. Secondary outcome variables were analyzed with a mixed model ANOVA including a random center effect. All analyses were by intention-to-treat and adjusted for confounders. Missing values were recalculated by multiple imputation. The robustness of the results was assessed in relation to the analysis of observed cases. Any discrepancies were analyzed on a case-by-case basis.

The economic evaluation was performed according to the CHEERS statement¹⁵. Both hospital and non-hospital resources were considered. Compensation for days off work was added. The total costs for each group were calculated by adding the cost of each individual patient. A cost-effectiveness analysis was performed to assess the incremental cost per adverse event avoided. The cost-effectiveness analysis explored uncertainty about the joint density of the cost-effectiveness differences and quantified the uncertainty surrounding the incremental cost-effectiveness ratio. The absence of a significant difference in the cost-effectiveness ratio, or in both, does not preclude the presentation of these data at the cost-effectiveness level^{16,17}. The cost difference was compared with standard parametric or nonparametric tests (Student's or MannWhitney test). The incremental cost difference was calculated using nonparametric bootstrap resampling with 1,000 replications.

Values of p < 0.05 were considered significant. Statistical analysis was performed with the SAS program (Version 9.3, SAS Institute, Cary, North Carolina, USA).

Results

During the study period, from 03/17/2015 to 07/24/16, 2,498 calls were included and randomized, 1,234 to the FTMA group and 1,264 to the control group. During the follow-up period, 195 patients withdrew from the study and in 36 were lost to follow-up (Figure 1). Complete information was obtained in 2,267 (91%) patients. Baseline characteristics were similar in the two study groups and it is noteworthy that the median age of the patients was 5 years (Table 1). No difference was observed between the two groups in terms of management time and reason for the call (Table 2). Telephone physician referrals were higher in the FTMA group [relative risk (RR) 1.85; 95% CI 1.36-2.52] (Table 2). Patients included in the FTMA group were less likely to consult in PC after hours, in the ED, or to be admitted to the hospital during the next 15 days after the initial call (RR 0.70; 95% CI 0.58-0.85) (Table 3).

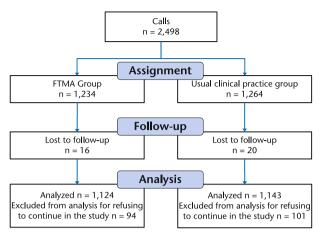


Figure 1. Flow diagram of the population studied.

No significant differences were found between the two groups in terms of EMS intervention, intensive care admission, mortality, morbidity, or symptom improvement. The satisfaction rate was over 89% in both groups. There were fewer ED visits (RR 0.69, 95% CI 0.48-0.97) in the intervention group (Table 3). Compliance with recommendations was high in both groups; for prescribed treatment it reached 89% and 94% and for dietary advice it was 94% and 96%, respectively. In the FTMA group there were 62% of patients who had at least one event during follow-up, in the usual care group it was 75%. Two patients in the usual clinical practice group died during follow-up. The circumstances of the deaths were not related to the study.

All patients were included in the economic analysis. The mean total cost was 91 euros in the FTMA group versus 150 euros in the standard care group (p < 0.01). Detailed medical costs are presented in Table 4. Days of sick leave did not differ between the groups, 5 days in the FTMA group and 4 days in the standard care group (p = 0.71). The FTMA group was more effective in preventing the use of emergency services and hospital admission, and at a lower cost than usual care. The combination of lower cost and greater effectiveness made telephone consultation a dominant strategy. We explored the uncertainty of these results with probabilistic sensitivity analysis using 1,000 replicates by resampling (Figure 2). The results of this analysis correspond to a two-dimensional confidence interval. Figure 2 shows that 96% of the points are in the quadrant where the FTMA group had a lower cost and was more effective than usual care.

Discussion

In this study, the FTMA group saw a decrease in the number of patients who required an out-of-hours faceto-face consultation in PC, or in an ED, or a hospital admission during the 15 days following the initial call. The economic analysis determined that the FTMA group had a lower cost.

Table 1. Baseline characteristics of the sample					
	Total N = 2,267 n (%)	FTMA Group N = 1,124 n (%)	Regular care group N = 1,143 n (%)	р	
Characteristics of the interlocutor					
Age (years) [median (IQR)]	35 (30-42)	34 (29-41)	35 (30-42)	0.28	
Sex (male)	385 (21)	186 (21)	199 (22)	0.75	
Relationship with the patient				< 0.001	
Patient	351 (16)	193 (17)	158 (14)		
Parent	1,626 (72)	820 (73)	806 (71)		
Partner	156 (7)	59 (5)	97 (9)		
Sibling	11 (1)	4 (0)	7 (1)		
Child	41 (2)	13 (1)	28 (3)		
Grandparent	26 (1)	14 (1)	12 (1)		
Cousin	1 (0)	0 (0)	1 (0)		
Friend	13 (1)	9(1)	4 (0)		
Other Characteristics of the patient	25 (1)	5 (0)	20 (2)		
Age (years) [median					
(ĬQR)]	5 (2-24)	5 (2-22)	4 (2-25)	0.58	
Sex (male)	1,062 (47)	513 (46)	549 (48)	0.25	
Previous disease	74 (2)	20 (4)	25 (2)	0.50	
Pulmonary Cardiac	74 (3)	39 (4)	35 (3)	0.59	
Neurological	62 (3) 30 (1)	25 (2) 13 (1)	37 (3) 17 (2)	0.14 0.49	
Renal	28 (1)	14 (1)	17 (2)	0.96	
Osteomuscular	29 (1)	12 (1)	17 (2)	0.38	
Psychiatric	16 (1)	10 (1)	6 (1)	0.30	
Other	146 (6)	65 (6)	81 (7)	0.21	
None	1,949 (86)	976 (87)	973 (85)	0.24	
Geographical area	, , , ,	. /	. /	0.20	
Rural	874 (40)	420 (38)	454 (41)		
Urban	1,339 (61)	681 (62)	658 (59)		
Reason for call				0.15	
Fever	1,275 (56)	615 (55)	660 (58)		
Symptoms of gastroenteritis	991 (44)	508 (45)	483 (42)		

FTMA: formalized telephone medical advice; CI: confidence interval; IQR: interquartile range.

It is important to emphasize the predominance of pediatric patients, since the median age of the series was 5 years. In previous studies carried out in the PC setting, the population under 5 years of age represented between 9% and 26% of patients^{2,9,18}. This fact could influence the cost analysis, with a lower number of prescribed sick leaves.

In order to reduce visits to the ED or face-to-face consultations with the PC physician, telephone helplines, telephone hotlines and telephone consultations have been proposed. In the ESTEEM study, the authors found that the introduction of PC physician or nurse telephone triage reduced the number of face-to-face contacts with the PC physician (RR 0.61; 95% CI 0.54-0.69)². Another study concluded that telephone consultation by nurses reduced the overall workload of the PC physician⁹. However, another study did not confirm these results⁵ and other studies showed a higher rate of

	Total N = 2,267 n (%)	FTMA group N = 1,124 n (%)	Regular care group N = 1,143 n (%)	Relative risk (95% Cl)	р
Duration of consultation in minutes [mean (SD)]	5.0 (0.8)	5.3 (0.7)	4.8 (1.0)	0.5 (0.3; 2.8)	0.65
Reason for consultation*					
Request for assessment	1,331 (61)	704 (64)	627 (58)	1.09 (0.76; 1.56)	0.64
Request for an ambulance	32 (2)	4 (0)	28 (3)	0.13 (0.02; 0.74)	0.02
Request for a doctor	807 (37)	389 (36)	418 (39)	0.91 (0.48; 1.74)	0.78
Response to consultation**					
Advice	1,375 (61)	901 (81)	474 (42)	1.85 (1.36; 2.52)	< 0.001
Schedule PC visit	338 (15)	206 (19)	132 (12)		
Telephone referral	1037 (46)	695 (62)	342 (30)		
Home visit	283 (13)	60 (5)	223 (20)		
Request firefighter	1 (0)	0 (0)	1 (0)		
Request ambulance	60 (3)	11 (1)	49 (4)		
Refer to ED	97 (4)	20 (2)	77 (7)		
Refer to PC on call	415 (19)	123 (11)	292 (26)		
Type of referral***					
Teleprescription	1,251 (56)	895 (82)	356 (31)	2.55 (1.95; 3.34)	< 0.001
Hygienic-dietary measures	1,429 (64)	1,011 (93)	418 (37)	2.53 (2.20; 2.91)	< 0.001
*Missing data in 97 parts.					

Table 2. Handling of telephone consultation

Missing data in 97 parts.

**Missing data in 20 parts.

***Missing data in 33 parts.

CI: confidence interval; PC: primary care; ED: emergency department; FTMA: formalized telephone medical advice; SD: standard deviation; ED: emergency department.

reconsultation during follow-up^{3,18,19}. In England, the introduction of a national nurse-led telephone helpline failed to reduce ambulance use and ED visits, and there was little effect on the overall demand for out-of-hours care²⁰. Regarding the effect on ED visits, the results of previous studies are controversial. A Cochrane review published in 2009 included five studies that showed no difference of telephone consultations on ED visits. One of these studies, which analyzed telephone consultations by nurses, found an increase in visits³.

This study shows very high compliance and satisfaction suggesting that the advice offered by physicians was well received by most callers. Our results show that compliance and self-reported satisfaction in the two groups is superimposable to other studies^{2,10,21}. This result is the same in the two groups, indicating that only counseling (formalized or not) is related to a high rate of satisfaction or compliance. Two subjects (0.1%) included in the usual care group died at home. These deaths were not associated with the advice given. Other previous studies obtained a similar morbidity rate^{2,10}. A study that included more than 10,000 patients found no relationship between telephone counseling and mortality⁹. Although the pres-

Table 3. Events during follow-up adjusted by reason for consultation

	Total N = 2,267 n (%)	FTMA group N = 1,124 n (%)	Regular care group N = 1,143 n (%)	Relative risk (95% CI)	р
Main variable					
Patients who visited the PC out of the working hours or in the ED or required hospital admission 15 days after the initial call	1,071 (47.2)	393 (35.0)	678 (59.3)	0.70 (0.58;0.85)	< 0.001
Secondary variable					0.04
Consultation in the ED	409 (18.0)	161 (14.3)	248 (21.7)	0.69 (0.48; 0.97)	0.09
Face-to-face consultation in PC (out of hours) or in the ED	1,672 (73.8)	752 (66.9)	920 (80.5)	0.88 (0.76; 1.02)	
Intensive care admission	8 (0.4)	2 (0.2)	6 (0.5)	0.37 (0.09; 1.49)	0.16
Firefighters or EMS intervention	34 (1.5)	7 (0.6)	27 (2.4)	0.44 (0.16; 1.24)	0.12
Death	2 (0.1)	0 (0.0)	2 (0.2)	n.c.	-
Patient deterioration	3 (0.1)	1 (0.1)	2 (0.2)	n.c.	-
Improvement of symptoms	2,217 (97.8)	1,102 (98.0)	1,115 (97.6)	1.00 (0.99; 1.01)	0.65
Additional telephone consultations	0.05 (0.02)	0.06 (0.02)	0.04 (0.01)	0.05 (0.02; 0.07)	0.20
Satisfied patient	2,032 (89.6)	1,006 (89.5)	1,026 (89.8)	1.00 (0.97; 1.02)	0.77
Patient satisfaction (numerical scale) (SD)	8.25 (0.22)	8.31 (0.30)	8.18 (0.15)	0.10 (0.05; 0.71)	0.74

n.c.: not calculable; PC: primary care; FTMA: formalized telephone medical advice; SD: standard deviation; CI: confidence interval; EMS: Emergency Medical Service.

Table 4. Economic evaluation

	Total N = 2,498 Mean (SD)	FTMA group N = 1,234 Mean (SD)	Regular care group N = 1,264 Mean (SD)	р
Visita programada en AP (€)	9 (15)	10 (17)	9 (14)	< 0.01
Visita en SU (€)	13 (31)	11 (30)	15 (32)	< 0.01
Ambulancia avanzada (€)	0.8 (8)	0.8 (8)	0.8 (7)	0.81
Trasporte sanitario (€)	2 (20)	0.6 (7)	3 (27)	< 0.01
Visita urgente en AP (€)	16 (26)	12 (24)	20 (28)	< 0.01
Ingreso hospitalario (€)	80 (546)	57 (444)	103 (629)	0.05
Total (€)	121 (560)	91 (457)	150 (644)	< 0.01

PC: primary care; FTMA: formalized telephone medical advice; SD: standard deviation; ED: emergency department.

ent trial was not designed to study safety, the results obtained confirm previous studies in which telephone advice given by nurses was not associated with increased morbidity. Other authors have studied the efficiency and cost of telephone consultations in acute triage and the use of telephone triage led by the PC physician cost approximately £75 per patient during a 28-day follow-up, a figure comparable to our results^{9,22}. We also observed a modest increase in PA contacts in the FTMA arm, which was more than offset by a reduction in ED visits and hospital admissions²³. It is possible that cost reduction and workload

40 €

redistribution could be optimized if telephone counseling were performed by nurses.

This study has several limitations. Firstly, it was carried out in a single country, so the results obtained could be different in other settings with a different health care system. However, the intervention was carried out for two very common reasons for consultation, such as fever and symptoms suggestive of gastroenteritis, so we believe that its implementation in other contexts could be studied. Secondly, the economic analysis did not include the cost of the on-call physician. This cost could be important in other health care systems. However, this underestimation of the cost of the procedure had no impact on our conclusions. Finally, 19% of patients did not receive medical advice in the FTMA group. It is possible that there is a subgroup of patients who may not receive FTMA. Further analyses have been proposed to identify this population and analyze the impact on this subgroup.

In conclusion, the results of this study suggest that the systematic use of FTMA in patients with fever or gastroenteritis could reduce the use of out-of-hours health care services within 15 days of the initial call. The use of telemedicine could be a simple, reliable and low-cost solution to respond to the increasing demand for health care without affecting existing after-hours services. Additional studies are needed to expand the indications for FTMA to other clinical scenarios.

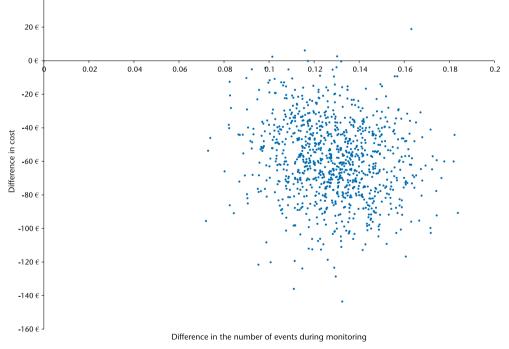


Figure 2. Cost-effectiveness graph showing the uncertainty about the difference in costs and emergency events between telephone consultation and standard care groups. The vertical axis represents the difference in cost and the horizontal axis the difference in effectiveness, the center is the cost and effectiveness of the standard of care. The 1,000 replicates show the uncertainty about the mean increase in the cost-effectiveness ratio and can be understood as the confidence interval of these results. The replicates on the right side of the plane indicate better effectiveness for the telephone consultation (100%) and the replicates at the bottom of the plane indicate that the use of a telephone consultation reduced total costs (96%).

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