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1 **“Thinking that somebody’s going to delay [a tonsillectomy] for one to two years is**  
2 **quite horrifying really”: A qualitative feasibility study for the NATional Trial of**  
3 **Tonsillectomy IN Adults (NATTINA Part 2)**

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30

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33 Running title:

34 Feasibility study for the NAtional Trial of Tonsillectomy in Adults

35 Key words:

36 Feasibility, Tonsillectomy, Recurrent sore throat, Patients, Clinicians

37

38

39 **Abstract**

40 *Objectives*

41 Level One Evidence on the value of adult tonsillectomy versus non-surgical management  
42 remains scarce. Before embarking on a costly national randomised controlled trial, it is  
43 essential to establish its feasibility.

44 *Design*

45 Feasibility study with in-depth qualitative and cognitive interviews.

46 *Setting*

47 ENT staff and patients were recruited from nine hospital centres across England and  
48 Scotland.

49 *Participants*

50 Patients who were referred for tonsillectomy (n=15), a convenience sample of General  
51 Practitioners (n=11) and Ear, Nose and Throat staff (n=22).

52 *Main outcome measures*

- 53 1. To ascertain whether Ear, Nose and Throat staff would be willing to randomise patients  
54 to the treatment arms.
- 55 2. To assess General Practitioners' willingness to refer patients to the National Trial of  
56 Tonsillectomy IN Adults (NATTINA) centres.
- 57 3. To assess patients' willingness to be randomised and the acceptability of the deferred  
58 surgery treatment arm.
- 59 4. To ascertain whether the study could progress to the pilot trial stage.

60

61 *Results*

62 Ear, Nose and Throat staff and General Practitioners were willing to randomise patients to  
63 the proposed NATTINA. Not all ENT staff were in equipoise concerning the treatment  
64 pathways. Patients were reluctant to be randomised into the deferred surgery group if they  
65 had already waited a substantial time before being referred.

66 *Conclusions*

67 Findings suggest that the National Trial of Tonsillectomy IN Adults may not be feasible.  
68 Proposed methods could not be realistically assessed without a pilot trial. Due to the  
69 importance of the question, as evidenced by NATTINA clinicians, and strong support from  
70 ENT staff, the pilot trial proceeded, with modifications.

## 71 **Introduction**

72 The role of tonsillectomy in managing adult sore throat remains uncertain, and despite  
73 demonstrable compliance with SIGN guidance <sup>(1)</sup>, UK regional variation in tonsillectomy  
74 rates persist <sup>(2)</sup>. Questions that stakeholders wish to answer relate to the relative costs and  
75 benefits of tonsillectomy against non-surgical pathways. The 2014 Cochrane review <sup>(3)</sup>  
76 identified two evaluable adult trials, with just 156 participants, both in Finland, and  
77 concluded that reasonable levels of evidence on effectiveness were still only available for  
78 children. Low recruitment rates into surgical randomised controlled trials (RCTs) threaten  
79 external validity of findings <sup>(4)</sup>. Integration of qualitative research can improve feasibility,  
80 design and conduct <sup>(5)</sup>. Additionally, recruitment processes should be tested before patients  
81 are enrolled to a trial <sup>(4, 6)</sup> However there is a paucity of research examining key  
82 stakeholders' experience of recurrent sore throats and attitudes towards management in  
83 adults.

84 The National Trial of Tonsillectomy In Adults (NATTINA) consists of this feasibility study, an  
85 internal pilot and definitive trial of 600 adults, with embedded qualitative process evaluation  
86 <sup>(7)</sup>. This paper, reporting the main findings from the feasibility study, follows a linked paper  
87 (Reference the linked NATTINA part 1 paper submitted separately) where stakeholders  
88 were asked their views of recurrent sore throat, tonsillitis and their management as part of  
89 this feasibility study. Gaining stakeholder perspectives of these issues was considered to  
90 be an essential part of the study, however the depth of findings allowed for two linked, but  
91 discrete papers to be completed.

92 In the main NATTINA trial participants will be randomly allocated into immediate or deferred  
93 surgery. Our experience of a randomised trial of tonsillectomy in children <sup>(8, 9)</sup>, together with  
94 other published Ear, Nose and Throat (ENT) surgical trials <sup>(3)</sup>, highlighted the problem of  
95 retaining participants in a non-surgical cohort. These findings along with patient and public  
96 engagement have influenced our trial design and decision to use deferred surgery as the  
97 conservative management option rather than no surgery.

98 The aim of the NATTINA feasibility study was to assess the practicality of the proposed  
99 internal pilot and full scale trial. The specific objectives of the study were to establish:  
100 standard NHS ENT staff willingness to randomise patients to the treatment arms; the  
101 feasibility of patient identification and the eligibility criteria ; GPs' willingness to refer  
102 patients to standard NHS NATTINA centres; patients' willingness to be randomised and  
103 their potential acceptance of the deferred surgery treatment arm, as well as views on the  
104 proposed data collection methods, including weekly sore throat alert prompts and Sore  
105 Throat Alert Returns (STARs)<sup>(7)</sup>.

## 106 **Methods**

### 107 ***Ethical considerations***

108 Favourable ethical opinion was given by proportionate review of the NRES committee –  
109 Fulham, London on 16 June 2014 (14/LO/1115).

### 110 ***Sampling***

111 Sampling of patients was purposive, seeking maximum demographic  
112 (age/sex/duration/severity). A convenience sample was selected from NHS staff likely to be  
113 involved in the nine UK standard NHS NATTINA centres and GPs from the surrounding  
114 catchment areas. Sample size was determined by reaching data saturation where the  
115 research team deemed no new themes to have emerged in three consecutive interviews  
116 <sup>(10)</sup>. Based on previous work by the investigators <sup>(11)</sup>, it was estimated that this plateau  
117 would occur at around 45+ interviews: 20 ENT staff, 15 patients and 10 GPs.

### 118 ***Procedure***

119 ENT staff identified patients who met the proposed NATTINA eligibility criteria <sup>(7)</sup>.  
120 Healthcare professionals (otolaryngologists, research nurses, nurse practitioners, clinic  
121 managers and general practitioners) who were likely to be involved at each NATTINA main  
122 trial site were identified. Written informed consent was taken before interviews.

123 In-depth interviews took place over 5 months (August 2014 to January 2015) and lasted up  
124 to 30 minutes. Interviews were based on flexible topic guides derived from the literature,  
125 issues raised by our Patient and Public Involvement group and in conjunction with the study  
126 Otolaryngologists and GP. Themes and topics explored included: symptoms and effects of



127 recurrent sore throats, management of recurrent sore throat, experience of participation and  
128 willingness to participate in research.

### 129 ***Data management and analysis***

130 Interviews were recorded and transcribed. Framework analysis<sup>(12)</sup> was supported by NVivo  
131 software<sup>(13)</sup>. Data were repeatedly read and coded by an experienced qualitative  
132 researcher LM within a framework of a priori issues and those identified by participants or  
133 which emerged from the data. Analysis was discussed at regular meetings of the research  
134 team to identify areas for closer consideration (including negative case analysis) and to  
135 enhance credibility of the thematic framework and interpretation<sup>(14)</sup>. Qualitative work  
136 explored influences on both patient recruitment and on the implementation of the study  
137 interventions. Analysis of barriers and facilitators to 1) trial participation and 2) the  
138 normalisation of study interventions in clinical practice was informed by Normalization  
139 Process Theory<sup>(15)</sup>.

### 140 **Results**

141 All nine study centres participated, with 48 participants interviewed. Staff were 9 ENT  
142 consultants, 1 ENT trainee (registrar), 6 research nurses, 4 nurse practitioners and 2 trial  
143 managers. Seven centres received 39 patient 'expression of interest' forms yielding 15  
144 (38%) patient interviews. Twelve patients were interviewed face-to-face and due to work  
145 commitments, 3 patients opted to be interviewed by telephone. At the time of their interview  
146 the patients were on the waiting list for a tonsillectomy; this was considered to be the most  
147 efficient form of recruitment. Contact details for 40 GPs were received from 7 of the centres;  
148 11 (28%) GPs were recruited. All but one of the ENT staff and GPs were interviewed by  
149 telephone. Results are presented by study objective with individual participant quotations  
150 used to support and illustrate the findings.

#### 151 ENT staff willing to consider participation in NATTINA

152 All interviewed staff were willing to participate in the NATTINA trial and to randomise  
153 patients, however, they questioned whether patients would be willing to accept  
154 randomisation:

155 *We don't know which arm you're better off being in. So I'm very happy*  
156 *randomising the patients. I don't know how acceptable it is to the patients*  
157 *we randomise*

158 Most ENT staff felt the research would address the fundamental question of whether  
159 tonsillectomy in adults was beneficial, not only to the patient but also for the NHS in terms  
160 of cost-effectiveness.

161 *I mean, whilst we've driven down the frequency of tonsillectomy and the so-*  
162 *called savings there, what we do see is an increase in people coming into*  
163 *hospital with acute tonsillitis*

164 The above respondent felt the implications of these 'so-called savings' were having a  
165 negative impact on patients' health. Many ENT staff felt that the evidence for surgery  
166 versus conservative management was scarce:

167 *..A lot of decisions are being made about how to treat patients with*  
168 *recurrent acute tonsillitis which don't have a robust evidence base behind*  
169 *them*

170 It was felt that new research evidence had the potential to improve patient care and  
171 practice.

## 172 Potential participants willing to take part in NATTINA

### 173 *Patients' views*

174 The majority of patients reported that they would not consider taking part in the proposed  
175 trial as they did not want the risk of being randomised to deferred surgery:

176 *..I'd be anxious to have the surgery sooner because I've been suffering*  
177 *since I was young...to wait even more and to miss more time off work, no I*  
178 *really think it's time that they come out*

179 Many patients reported the negative effects of tonsillitis and felt that to defer surgery would  
180 be too detrimental to their quality of life:

181 *It had too much of an impact. It was happening at least twice a month as*  
182 *well, so it was really interfering with my attendance and stuff, and work, and*  
183 *money*

184 Some patients stated they might consider randomisation if they knew they could opt out of  
185 the deferred surgery group without having to go back to the bottom of the surgery waiting  
186 list if their symptoms worsened:

187                    *Yeah, that would probably be better. I wouldn't want to be in the position*  
188                    *where you have to wait and wait and wait to get re-referred and re-seen*  
189                    *and stuff like that*

190    *GPs' views*

191    Many GPs believed that tonsillectomy in adults was a rare occurrence and they were under  
192    pressure to minimise referrals to secondary care. Some felt that adults were not looking for  
193    surgery:

194                    *We try really hard not to send our patients because for the vast majority of*  
195                    *patients they are unlikely to have their tonsils removed as adults*

196    However, those GPs that did refer patients felt the patients would probably be unwilling to  
197    be randomised as, having had to meet strict criteria before being referred<sup>(1)</sup>, GPs felt that by  
198    the time the patient reaches the consultant they have an expectation of surgery:

199                    *Certainly, I do not refer very many people, and the ones that I do, I do not*  
200                    *think they would be willing to say "Great, I will enter a trial and wait up to*  
201                    *another two years"*

202    As with the actual patients themselves, a couple of GPs reported that the option to change  
203    to immediate surgery if withdrawing from the deferred surgery group may persuade some  
204    patients to be randomised:

205                    *I think that sounds very reasonable. I like the get out clause in the control*  
206                    *arm, but I think it's a very good idea to delay surgery anyway*

207    *ENT staff views*

208    Most ENT staff concurred with GPs' views of patients having expectation of surgery, not  
209    willing to defer surgery, or that they may be more willing to be randomised with a quicker  
210    'opt-out' route:

211                    *Most patients in my experience do come with the view point that they would*  
212                    *like the tonsils removed 'cos a lot of them have already discussed it with*  
213                    *the GP. So asking them to wait another year, I'm not sure if we'll be able to*  
214                    *recruit that many patients to that arm*

215

216 Treatment pathways acceptable and adequately defined

217 *Patients' views*

218 Participants' reactions were closely related to whether they would be willing to be  
219 randomised and take part in the trial. That is, they were not willing to accept the risk of  
220 being randomised into the deferred surgery group as they found that pathway, as originally  
221 presented, to be unacceptable:

222 *I don't even want to imagine what that would be like [deferred surgery].*  
223 *Tonsillitis is honestly one of the worst illnesses I've had, and needs to be*  
224 *treated sooner rather than later.*

225 *GPs' views*

226 A few GPs felt that deferring surgery was a good idea but were unsure how it would be  
227 accepted by patients:

228 *I think that's entirely appropriate. My only concern is the non-surgical*  
229 *treatment plan you might lose patients who then go on to decide that they*  
230 *want surgery... because they are having difficulty with their symptoms*

231 *ENT staff*

232 Some ENT staff identified concerns over the treatment pathways with one practitioner  
233 worried that patients may feel they were being disadvantaged by being randomised to the  
234 deferred surgery arm; one research nurse felt that delaying a patient's surgery was not  
235 acceptable:

236 *Thinking that somebody's going to delay that [a tonsillectomy] for one to*  
237 *two years is quite horrifying really*

238 Outcome measures and data collection methods feasible and adequately defined

239 *Patients' views*

240 Most patients found the outcome measures and data collection methods acceptable with  
241 most happy to use electronic methods (email and text) to communicate and complete tasks.  
242 A small selection of patients reported that they preferred paper-based methods but  
243 understood that email would be quicker and cheaper.

244 Patients reported that they would be willing to complete the STAR text alerts, however  
245 some felt weekly to be too onerous:

246 *I'd probably get quite irritated after a while like weekly seems just too close*  
247 *together. Maybe like fortnightly would be a better idea*

#### 248 *ENT Staff views*

249 Some staff felt that data collection was an on-going research issue and that some patients  
250 may find the methods intensive. Paper-based methods were stated as rarely successful  
251 and there was concern weekly alerts may be too burdensome.

252 However, there was general consensus that electronic methods would be suitable:

253 *The demographic of recurrent tonsillitis tends to be younger patients, so I*  
254 *think things like text messaging questionnaire [sic], etc. would probably*  
255 *give you a higher response rate than a traditional paper-based through the*  
256 *post questionnaire.*

257 However, one staff member was concerned that not everyone would have access to the  
258 internet. Additionally it was suggested that patients, not currently suffering symptoms,  
259 would be disinclined to respond to prompts for outcome data. Furthermore, staff from two of  
260 the centres reported high numbers of patients whose first language was not English:

261 *The only issue is the language barrier for some patients, which where I*  
262 *work, my patient population, that's quite a big issue.*

#### 263 Process of patient identification and recruitment feasible and adequately defined

#### 264 *GPs' views*

265 Most GPs stated that they were willing to refer patients to centres participating in NATTINA  
266 but there were some queries about how the referral process would work:

267 *It is maybe thinking about, in terms of the study design, people at the point*  
268 *of referral knowing, or the point they receive their outpatient at clinic is*  
269 *probably better...that gives them the chance to almost revisit why they*  
270 *have been referred, and what their expectations are .*

271 Many GPs thought it beneficial for practices to be study aware so they could provide  
272 patients with information to ensure that patients are referred without a prior expectation of  
273 tonsillectomy.

## 274 **Discussion**

### 275 ***Synopsis of key findings***

276 Results suggest that ENT staff are strongly supportive of a trial of tonsillectomy in adults  
277 and are willing to randomise patients meeting SIGN criteria<sup>(1)</sup>. However patients meeting  
278 NATTINA eligibility criteria expressed reluctance to be randomised because of  
279 unwillingness to enter the deferred surgery arm of the study. Patients indicated that they  
280 might be more willing to be randomised if there was a clear route back to surgical  
281 intervention - at the time of their interview most patients had received a surgery date for  
282 their tonsillectomy or one was imminent. This inevitably contributed to their negative  
283 perception of deferral. There is a lot of emotion associated with surgery and, whilst waiting,  
284 patients are often preoccupied with issues such as feeling 'in limbo', 'lives being on hold'  
285 and 'clock-watching'<sup>(16, 17)</sup>.

286 Many GPs believed tonsillectomy in adults was a rare occurrence. However, in 2013-14,  
287 20,607 adults over the age of 16 years received a tonsillectomy in England i.e. the average  
288 GP will refer 2 patients (who receive a tonsillectomy) every 3 years<sup>(18)</sup>. In this study it was  
289 reported that some GP practices were encouraged to minimise tonsillectomy referrals; it  
290 has been estimated that two thirds of Clinical Commissioning Groups restrict referrals for  
291 treatments they deem to be non-urgent or of low clinical value<sup>(19)</sup>. This means that  
292 treatment control pathways have changed, moreover, some GPs stated they very rarely  
293 saw patients who were eligible for referral.

### 294 ***Implications for pilot trial***

295 The feasibility trial allowed for timely modifications and valuable stakeholder insights. The  
296 Trial Management Group assessed the feasibility results and implemented several  
297 changes, specifically around movement between treatment arms. The proposal that  
298 patients who wanted to switch from the deferred surgery group could do so without going  
299 back on the waiting list resulted in positive feedback from patients. This proposal arose  
300 from a research team meeting to discuss interim analysis of the feasibility study and  
301 feedback from the patient involvement panel. It was proposed that reduced waiting for

302 patients who decide to switch may be enough of an incentive for some patients to  
303 participate. Random allocation to treatment arms within NATTINA will be concealed from  
304 investigators, GPs, ENT staff and participants in order to eliminate bias however, anything  
305 which facilitates movement between arms has the potential to impact on the intention to  
306 treat analysis; therefore, it was recommended that a per-treatment analysis was also  
307 conducted and that numbers switching are monitored throughout the recruitment period to  
308 assess impact on trial design. The following changes were also recommended:

- 309 • Emphasis on the need for a trial in the patient information materials
- 310 • Spread the recruitment to the pilot to a larger number of centres
- 311 • Refinement of baseline questionnaire
- 312 • Translation of patient study information to Urdu, Gujarati, Punjabi and Bengali
- 313 • Clarification of clinical pathway for control (deferred-surgical) arm for participants
- 314 • Extra attention to dissemination of information about the study to GPs, to mitigate  
315 patient expectation that referral equates to tonsillectomy

316

### 317 ***Strengths and limitations***

318 A unique strength of this study is the quantity of appropriately representative data from  
319 multiple stakeholders. However, the fact that we selected patients who had already decided  
320 to proceed with a tonsillectomy inevitably must have influenced their perception of the  
321 study.

### 322 ***Conclusions***

323 The proposed methods were generally acceptable notwithstanding some concern about the  
324 weekly frequency of sore throat episode recording. ENT and research staff stated that the  
325 acceptance of the data collection methods could not realistically be assessed until a pilot  
326 trial was in operation. A decision-making meeting was scheduled for the end of the  
327 feasibility study to review the findings and to confirm that there was sufficient support from  
328 those interviewed to allow the project to continue on to the NATTINA internal pilot phase.  
329 The decision to continue was approved by the NATTINA Trial Steering Committee and HTA  
330 informed. Barriers to recruitment which may emerge include: fewer eligible patients than  
331 expected, smaller percentage of patients agreeing to participate, internal staff problems, <sup>(20)</sup>  
332 and lack of equipoise <sup>(21)</sup>.

333

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