

BMJ Open

BMJ Open is committed to open peer review. As part of this commitment we make the peer review history of every article we publish publicly available.

When an article is published we post the peer reviewers' comments and the authors' responses online. We also post the versions of the paper that were used during peer review. These are the versions that the peer review comments apply to.

The versions of the paper that follow are the versions that were submitted during the peer review process. They are not the versions of record or the final published versions. They should not be cited or distributed as the published version of this manuscript.

BMJ Open is an open access journal and the full, final, typeset and author-corrected version of record of the manuscript is available on our site with no access controls, subscription charges or pay-per-view fees (<http://bmjopen.bmj.com>).

If you have any questions on BMJ Open's open peer review process please email info.bmjopen@bmj.com

BMJ Open

Prevalence of rotator cuff tendinopathy and the resulting impact on health services: the Chingford general population cohort

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2021-059175
Article Type:	Original research
Date Submitted by the Author:	15-Nov-2021
Complete List of Authors:	Hinsley, Hannah; University of Oxford Nuffield Department of Orthopaedics Rheumatology and Musculoskeletal Sciences Ganderton, Charlotte; Swinburne University of Technology Faculty of Health Arts and Design, Nursing and Allied Health Arden, Nigel; University of Oxford , University of Oxford Nuffield Department of Orthopaedics Rheumatology and Musculoskeletal Sciences, Carr, Andrew; University of Oxford, University of Oxford Nuffield Department of Orthopaedics Rheumatology and Musculoskeletal Sciences,
Keywords:	Shoulder < ORTHOPAEDIC & TRAUMA SURGERY, Ultrasonography < OBSTETRICS, Musculoskeletal disorders < ORTHOPAEDIC & TRAUMA SURGERY, Diagnostic radiology < RADIOLOGY & IMAGING

SCHOLARONE™
Manuscripts



I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our [licence](#).

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which [Creative Commons](#) licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

1
2
3 1 **Prevalence of rotator cuff tendinopathy and the resulting impact on health services: the**
4 2 **Chingford general population cohort**
5 3

6 4 Hannah Hinsley^{1*}, Charlotte Ganderton², Nigel Arden^{1^}, Andrew Carr^{1^}

7 5 ¹ The Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, University
8 6 of Oxford, Oxford, United Kingdom

9
10
11 7 ² Department of Health Sciences and Biostatistics, Faculty of Health Arts and Design, Swinburne
12 8 University of Technology, Hawthorn, Victoria, Australia
13 9

14
15 10 **Author information:**

16 11 Dr Hannah Hinsley; Orthopaedic Surgeon, ARUK orthopaedic clinical research fellow, The Nuffield
17 12 Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, University of Oxford,
18 13 United Kingdom; hannah.hinsley@nhs.net
19 14

20 15 [^]Professor Nigel Arden; Lead of Musculoskeletal Epidemiology, Deputy Director Centre for Sport,
21 16 Exercise & Osteoarthritis Research Versus Arthritis and Fellow at the Lady Margaret Hall at The
22 17 Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, University of
23 18 Oxford, United Kingdom; nigel.arden@ndorms.ox.ac.uk
24 19

25 20 Dr Charlotte Ganderton, Physiotherapist and Lecturer at the Department of Health Sciences and
26 21 Biostatistics, Faculty of Health Arts and Design, Swinburne University of Technology, Hawthorn,
27 22 Victoria, Australia, cganderton@swin.edu.au
28 23

29 24 [^]Professor Andrew Carr, Professor of Orthopaedics at The Nuffield Department of Orthopaedics,
30 25 Rheumatology and Musculoskeletal Sciences, University of Oxford, United Kingdom; Director of the
31 26 Botnar Research Centre; andrew.carr@ndorms.ox.ac.uk
32 27

33 28 *Corresponding author: Dr Hannah Hinsley

34 29 Contact address: Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences,
35 30 NIHR Biomedical Research Unit, Botnar Research Centre, University of Oxford, Nuffield
36 31 Orthopaedic Centre, Windmill Road, OX3-7LD Oxford, United Kingdom
37 32

38 33 [^]Senior co-authors
39 34
40 35
41 36
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

1
2
3 37 **Contributors:** HH, NA, AC were responsible for planning, conducting, and reporting the work
4 38 described in the article. HH and CG drafted the manuscript. All authors approved the final version of
5 39 the article. HH, NA and AC had access to all the data in the study and can take responsibility for the
6 40 integrity of the data and the accuracy of the data analysis. HH is guarantor. The corresponding author
7 41 attests that all listed authors meet authorship criteria and that no others meeting the criteria have been
8 42 omitted. All authors fully acknowledge the contribution of the patients that participated in this study.
9 43 No authors are employees of the National Institutes of Health.

12
13 44 **Transparency Statement:** The lead author (the manuscript's guarantor) affirms that the manuscript
14 45 is an honest, accurate, and transparent account of the study being reported; that no important aspects
15 46 of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant,
16 47 registered) have been explained.

18 48
19 49 **Role of the funding source:** Arthritis Research United Kingdom awarded the project £190,361.00 to
20 50 cover costs to completion. Researchers were independent from the funding body. All authors, external
21 51 and internal, had full access to all the data (including statistical reports and tables) in the study and
22 52 can take responsibility for the integrity of the data and the accuracy of the data analysis.

23 53
24 54 **Competing interests:** No competing interests

25 55
26 56 **Ethics approval:** Outer North East London Research Ethics Committee (formerly Barking and
27 57 Havering and Waltham Forest RECs), LREC (R&WF) reference ID = 96.

28 58 29 59 **Patient and public involvement**

30 60 We would like to thank all the participants of the Chingford Women Study for their time.
31 61 We would also like to thank Mrs Maxine Daniels and Dr Alan Hakim for their time and dedication,
32 62 and both Mr Alex Nichols and Mr Michael Daines for their assistance with data collection and Dr
33 63 Gemma Wallis for her assistance with data analysis.

34 64 35 65 **Acknowledgement**

36 66 Thank you to Dr Gemma Wallis, Statistician, for reviewing statistical analysis processes used in this
37 67 study.

38 68
39 69 **Data sharing:** For information about the Chingford 1000 Women Study,
40 70 email chingford@ndorms.ox.ac.uk.

41 71
42 72 **Dissemination to participants and related patient and public communities:** We will disseminate
43 73 our findings to patient organisations and media outlets.

44 74
45 75 **Provenance and peer review:** Not commissioned; peer reviewed at Orthopaedic meetings.
46 76

Structured Abstract

Objectives:

To define the population prevalence of rotator cuff tears and test their association with pain and function loss in a general population cohort. Secondly, to determine the impact of shoulder pain in association with rotator cuff tears on primary healthcare services.

Design:

Cross sectional observational study.

Participants:

Individuals were part of the Chingford 1000 women cohort, a 20-year-old longitudinal population study comprising 1003 women aged between 64 and 87, and representative of the population of the UK.

Main outcome measures:

To compare symptoms across stages of rotator cuff tendinopathy using the Oxford shoulder score, and to quantify resultant GP consultations.

Results:

The population prevalence of full-thickness tears was 22.2%, which increased with age ($p<0.001$), and in the dominant arm (RR 1.64, $p<0.001$).

Although 48.4% of full-thickness tears were asymptomatic there was an association between rotator cuff tears and patient reported symptoms. Individuals with at least one full-thickness tear were 1.97 times more likely, than those with bilateral normal tendons ($p<0.001$), to have symptoms. Severity of symptoms it not related to the severity of the pathology until tears are $>2.5\text{cm}$ ($p=0.009$).

8.9% of the cohort had seen their GP with shoulder pain and a full-thickness rotator cuff tear, 18.8% with an abnormality and 29.3% overall.

Conclusion:

Rotator cuff tears are common, and primary care services are heavily impacted. As 50% of tears remain asymptomatic, future research may investigate the cause of pain and whether different treatment modalities, aside from addressing the pathology, need further investigation.

Trial Registration:

The local ethics committee approved the study (Outer North East London Research Ethics Committee (formerly Barking and Havering and Waltham Forest RECs), LREC (R&WF) reference ID = 96).

Strengths and limitations of this study:

- Pain on the Oxford Shoulder Score is associated with the presence of rotator cuff tendinopathy, but not the extent of structural pathology identified on ultrasound imaging.
- Rotator cuff tendinopathy poses a large burden on the healthcare system with 28.8% of people seeking GP consultation for their shoulder pain.
- This epidemiological study demonstrates association but not causality and leaves unanswered questions as to what additional factors contribute to shoulder pain.

125 **Introduction**

126 Musculoskeletal pain is one of the most common sources of disability in the Western world¹. The
127 shoulder is the third most common site of musculoskeletal disease², with an estimated 20% of the
128 population reporting pain at any given time³. Pain related to rotator cuff tears are estimated to account
129 for 30-40% of these shoulder complaints⁴, causing high levels of disability and associated healthcare
130 costs⁵⁻⁷. High-definition ultrasound is the current gold standard for the detection of full-thickness
131 tears, and is a valid tool to detect an abnormal tendon enthesis⁸, but has poorer accuracy to detect
132 partial-thickness tears⁸⁻¹⁴. Full thickness tears are recognised to be common and associated with
133 increasing age¹⁵⁻¹⁸, however, prevalence in symptomatic and asymptomatic shoulders varies widely
134 across cadaveric¹⁹, radiological¹⁹ and retrospective cohort studies^{16-18 20-28}. Furthermore, the presence
135 of selection bias in studies undertaken in rotator cuff tendon tears¹⁶⁻²⁸, has meant population-based
136 studies available, are not representative of Western demographics. Thus, research in this area may
137 lead to a better understanding of the natural history of rotator cuff tears.

139 Clinical manifestations of rotator cuff tears are varied^{15 17 22 26 28}, and detection of pathology and its
140 relationship to clinical symptoms is not well established. Many tears are asymptomatic but are
141 thought to be at risk of developing symptoms with time²⁶. Although larger tears are more likely to be
142 painful, there is also no evidence to suggest that they have a greater severity of symptoms than
143 smaller tears²⁹. One population cohort from a mountainous region has suggested that only a third of
144 full-thickness tears were painful, of which symptoms were more prevalent in the dominant arm³⁰.
145 Though, all studies investigating symptom association have looked at isolated shoulders, and have not
146 considered that the individual, who has two shoulders, may have a significant influence on symptoms
147 rather than solely the underlying pathology. To date, no study has explored the association between
148 rotator cuff tears, pain and functional loss in a general population cohort, or how these impact on a
149 health service.

151 This study aims to: (i) describe the population prevalence of different stages of rotator cuff tear in a
152 general population cohort of women; (ii) determine what proportion of rotator cuff tears are
153 symptomatic, and whether the severity of symptoms correlates with tear stage severity; (iii) identify
154 individual influences on the likelihood of symptoms and (iv) quantify the impact of symptomatic
155 rotator cuff tears on primary health care services.

157 **Methods**

158 *Design*

159 Study participants were identified from the Chingford Study, a well described prospective population-
160 based longitudinal study of osteoarthritis and osteoporosis, comprising 1003 women, derived from the
161 register of a large general practice in Chingford, North London³¹⁻³³. The women aged 44-67 years at
162 baseline are representative of women in the UK general population with respect to weight, height, and
163 smoking characteristics. The study was established in 1989 and 516 women attended the year 20
164 follow-up visits. A musculoskeletal assessment, including the Oxford shoulder score, and bilateral
165 shoulder ultrasound examination was performed in 463 women (of the original 1003, 158 women had
166 died, 111 were unable to attend, 218 had moved away or been lost to follow up, 52 attended the year
167 20 visit but did not have a shoulder assessment due to lack of assessor, and 1 did not complete an
168 Oxford shoulder score). The local ethics committee approved the study and consent was obtained
169 from each woman (Outer North East London Research Ethics Committee (formerly Barking and
170 Havering and Waltham Forest RECs), LREC (R&WF) reference ID = 96).

1
2
3 172 *Outcome measures:*

4 173 Participant characteristics of age, height, weight, hand dominance, and a self-reported
5 174 musculoskeletal questionnaire filled out a priori (including the Oxford Shoulder Score^{34 35}, body chart
6 175 and questions regarding previous pain, treatments and whether medical advice has been sought), were
7 176 all collected at baseline. A musculoskeletal ultrasound assessment on bilateral shoulders was then
8 177 undertaken using a fixed SOPP (standard operating procedure protocol).

9 178
10 179 The ultrasound examination of the 464 women was completed by two orthopaedic assessors and
11 180 performed using a GE voluson i-portable ultrasound machine with a 10-16MHz linear probe.
12 181 Ultrasound training and appropriate validation studies³⁶ were completed as recommended by the
13 182 BESS focus group - 343 individuals were scanned by assessor 1 and 121 individuals by assessor two.
14 183 Appropriate inter and intra-rater reliability studies were performed and showed high reproducibility
15 184 (weighted kappa 0.92 $p < 0.001$) and no difference in reporting trends ($p = 0.08$). The ultrasound
16 185 protocol was derived according to the recommendations of the Nuffield Orthopaedic Centre
17 186 Musculoskeletal radiology department. Tendons were classified into one of four working groups
18 187 based upon ultrasound measurements as validated by Hinsley et al.⁸: (i) normal tendon; (ii) abnormal
19 188 tendon and partial thickness tear; (iii) single tendon full-thickness tears (0-2.5cm) and (iv) multi-
20 189 tendon full-thickness tears (> 2.5 cm) (Figure 1).

21 190
22 191 Figure 1: Ultrasound images

23 192 *Data Analysis*

24 193 All statistics were performed using IBM SPSS Statistics version 22 (IBM, Armonk, NY, USA).
25 194 Age, BMI, hand dominance, and symptom presence were compared across the four different
26 195 tendinopathy groups. Wilcoxon rank sum test, one-way ANOVA, and chi-squared tests were used for
27 196 non-normal, normal and categorical data respectively.

28 197
29 198 Population prevalence of full-thickness tears was defined as having at least one unilateral full-
30 199 thickness tear. Population prevalence of tendon abnormalities was defined as having at least a
31 200 unilateral tendon abnormality ranging from abnormal enthesis to a full thickness tear. This was
32 201 calculated by summing the percentage with unilateral tears and the percentage with bilateral tears for
33 202 each age group.

34 203
35 204 Binary symptoms were defined using a dichotomised Oxford shoulder score^{34 35} where, any non-
36 205 perfect score ($\leq 47/48$) was classified as symptomatic. Where questions are pain specific, the four
37 206 pain specific questions of the OSS were used as a sub-scale. In symptomatic participants, the full OSS
38 207 scale, scored on a 0-48 point scale, was used to define symptom severity. A χ^2 test was used to
39 208 determine any difference between tendinopathy groups. Multivariate binary logistic regression was
40 209 used to adjust for the potential confounders age, BMI and hand dominance determined a priori. To
41 210 account for a high positive skew of the OSS data, all asymptomatic shoulders were removed, and a
42 211 logarithmic transformation of the inverse OSS was used to create a normal distribution. Symptom
43 212 severity in symptomatic shoulders was compared across tendinopathy groups using a 1-way ANOVA.
44 213 Multivariate linear regression was used to adjust for potential confounders age, and hand dominance
45 214 determined a priori.

215 Results

216 464 individuals (928 shoulders) were included in the study (Table 1). The distribution of age across
 217 each tendinopathy group was significantly different ($p<0.001$), with age increasing in accordance with
 218 tear severity. There was a statistical difference in the proportion of dominant and non-dominant arms
 219 in each tendinopathy group ($p=0.033$), with there being significantly more non-dominant arms in the
 220 normal tendon group ($p=0.010$), and significantly more dominant arms in those with full-thickness
 221 tears ($p=0.026$). There were no between-group differences in BMI ($p=0.080$).

222
 223 Table 1. Demographics of shoulders included in the study

	Frequency	%	Median age	Mean BMI	Dominant arm (%)
Normal	510	55.0%	70	27.5	46.1%
Abnormal/ Partial tear	294	31.7%	73	28.0	52.7%
Full-thickness tears (0-2.5cm)	85	9.2%	74	27.9	58.8%
Full-thickness tears (>2.5cm)	39	4.2%	74	29.6	61.5%
All	928	100%	71	27.8	50%

224 Prevalence of rotator cuff tendinopathy

225 The population prevalence of having at least one full-thickness tear was 22.2% (4.5% bilateral). For
 226 age groups 60-69, 70-79 and 80-89 these were 14.9%; 25.9% and 29% respectively, and bilateral tears
 227 2.3%; 5.9% and 5.8% respectively. The difference in prevalence between age groups was statistically
 228 different ($p<0.001$).

229
 230 The population prevalence of having at least a unilateral tendinopathy or tear was 59.5% (30.6%
 231 bilateral). For age groups 60-69, 70-79 and 80-89 these were 51.5%; 61.8% and 72.5% respectively,
 232 and bilateral tears 24.6%; 32.3% and 40.6% respectively. The difference in population prevalence
 233 between age groups was statistically significant ($p<0.001$).

234
 235 Table 2 shows the prevalence of rotator cuff tendinopathy in the dominant and non-dominant arms in
 236 age deciles. The distribution of tendinopathy differed between age groups (Dominant arm $p=0.002$;
 237 non-dominant arm $p=0.037$) with more pathology found in older age groups, and in the dominant
 238 compared to non-dominant arms ($p=0.004$). There was no difference in prevalence according to BMI
 239 group. The relative risk of full-thickness tear was 1.64 (1.073-2.326, $p=0.021$) in the dominant
 240 compared to non-dominant arm. For those aged 70-79 it was 2.072 (1.286-3.190, $p=0.002$), and aged
 241 80-89 was 2.293 (1.264-4.027, $p=0.006$), compared to those aged 60-69.

242
 243 Table 2. Prevalence of rotator cuff tendinopathy according to age decile and arm dominance

	Age Group							
	60-69 (n=175)		70-79 (n=220)		80-89 (n=69)		Total (n=464)	
	Count	%	Count	%	Count	%	Count	%
Dominant arm								
Normal tendon	102	58.3%	111	50.5%	22	31.9%	235	50.6%
Abnormal tendon/Partial thickness tear	54	30.9%	67	30.5%	34	49.3%	155	33.4%
Full-thickness tear 0-2.5 cm	14	8.0%	27	12.3%	9	13.0%	50	10.8%
Full-thickness tear >2.5 cm	5	2.9%	15	6.8%	4	5.8%	24	5.2%
Non-dominant arm								
Normal tendon	115	65.7%	122	55.5%	38	55.1%	275	59.3%

	Age Group							
	60-69 (n=175)		70-79 (n=220)		80-89 (n=69)		Total (n=464)	
	Count	%	Count	%	Count	%	Count	%
Dominant arm								
Normal tendon	102	58.3%	111	50.5%	22	31.9%	235	50.6%
Abnormal tendon/Partial thickness tear	54	30.9%	67	30.5%	34	49.3%	155	33.4%
Full-thickness tear 0-2.5 cm	14	8.0%	27	12.3%	9	13.0%	50	10.8%
Full-thickness tear >2.5 cm	5	2.9%	15	6.8%	4	5.8%	24	5.2%
Abnormal tendon/Partial thickness tear	49	28.0%	70	31.8%	20	29.0%	139	30.0%
Full-thickness tear 0-2.5 cm	10	5.7%	18	8.2%	7	10.1%	35	7.5%
Full-thickness tear >2.5 cm	1	0.6%	10	4.5%	4	5.8%	15	3.2%

244

245 *Association of symptoms (all shoulders)*

246 An analysis of symptom association was completed in 926 shoulders (463/464 participants due to loss
 247 of one questionnaire). There were 289 (31.2%) symptomatic shoulders according to a dichotomised
 248 OSS. The presence of symptoms was statistically significant between tendon groups ($p<0.001$);
 249 51.6% of all full-thickness tears were symptomatic. There was no difference in age, BMI or arm
 250 dominance between symptomatic or asymptomatic shoulders. The relative risks of having symptoms
 251 compared to those with a reported normal tendon were as follows: Abnormal/Partial tears 1.969; full-
 252 thickness tears 0-2.5cm 2.203; and full-thickness tears >2.5cm 4.718. All were significant ($p<0.001$)
 253 with the model correctly predicting 71% of symptom outcomes correctly.

254

255 Figure 2. Distribution of symptoms across each tendon group

256 *Symptom severity*

257 For the 289 symptomatic shoulders the full OSS was reported (Table 3). Median age was significantly
 258 different between groups ($p=0.047$), with age increasing with tear stage severity. No statistically
 259 significant between-group differences in BMI were identified, nor any within-group differences for
 260 arm dominance.

261

262 Table 3. Symptom severity demographics

	N	Median age	Mean BMI	Dominant arm (%)
Normal	116	70	28.3	46.6%
Abnormal/Partial tear	109	73	28.4	54.1%
Full-thickness tears 0-2.5cm	35	72	28.1	62.9%
Full-thickness tears >2.5cm	29	73	30.3	58.6%
All	289	71	28.5	50%

263

264 The mean OSS for symptomatic shoulders was 41.8. For normal tendons this was 42.5, abnormal
 265 tendons, 42.1; full-thickness tears (0-2.5cm), 40.2; and full-thickness tears (>2.5cm), 38.4. There was
 266 a statistical difference between the groups (1 way ANOVA $p=0.030$). Linear regression analysis after
 267 adjustment for age, BMI, and hand dominance (no interactions identified), showed that the only
 268 significant difference in OSS scores was between normal tendons (mean OSS 42.5) and large full-
 269 thickness tears (OSS 38.3), $p=0.009$, power 0.75 (overall model $p=0.007$, power 0.892).

270

271 *Association of symptoms (individuals)*

272 Table 4 shows the relationship between the individual, presence of full-thickness rotator cuff tear and
 273 the likelihood of symptoms. A clustering effect of bilateral symptoms or lack thereof is present,
 274 irrespective of the underlying pathology. After adjustment for age and BMI, compared to those with
 275 bilaterally normal shoulders the relative risk of having at least one symptomatic shoulder in the
 276 presence of a full thickness rotator cuff tear is 1.49, and 1.97 in the presence of at least a unilateral
 277 abnormality or cuff tear.

279 Table 4. Distribution of individual shoulder symptoms according to the presence of full-thickness
 280 tears

	No Symptoms	Unilateral Symptoms	Bilateral Symptoms	Total
Bilateral No FTT	226	71	63	360
Unilateral FTT	33	25	24	82
Bilateral FTT	10	3	8	21
Total	269	99	95	463

281 *Shoulder pain and use of primary care health services*

282 Table 5 shows the proportion of individuals with shoulder pain, past or present, seeking medical
 283 advice. The likelihood of seeking medical attention for shoulder pain was statistically different
 284 between each pathology group (Chi² test p=0.005) reflecting the increasing likelihood of pain.
 285 However, of those with pain the likelihood of seeking medical attention was not statistically different
 286 between groups (Chi² test p=0.179). Overall, 28.3% (131/463) of all individuals had at some stage
 287 seen their GP for shoulder pain. 8.9% (41/463) of this cohort had seen their GP with shoulder pain
 288 and a full-thickness tendon tear and 18.8% (87/463) had seen their GP with an abnormal tendon or
 289 full thickness tear.

291 A multivariable regression model using all individuals was used to predict the likelihood of attending
 292 a GP for shoulder pain. The presence of at least one full-thickness tear had a relative risk of 1.6
 293 compared to those with normal tendons of attending the GP. There was no statistical difference in
 294 relative risk of those with any tendon abnormality compared to those with bilaterally normal
 295 shoulders.

297 Table 5. Proportion of individuals seeking medical advice

	Present symptoms (either shoulder)		Past or Present symptoms (either shoulder)		All individuals % seen GP
	%	% seen GP	%	% seen GP	
All individuals (n=463)	41.9 (n=194)	44.8 (n=87)	55.7 (n=258)	50.8 (n=131)	28.3 (n=131)
Bilaterally normal tendons (n=187)	29.9 (n=56)	41.1 (n=23)	48.1 (n=90)	48.9 (n=44)	23.5 (n=44)

At least one abnormality (no tear) (n=173)	45.1 (n=78)	41.0 (n=32)	57.2 (n=99)	46.5 (n=46)	26.6 (n=46)
At least one full- thickness tear (n=103)	58.3 (n=60)	53.3 (n=32)	67.0 (n=69)	59.4 (n=41)	39.8 (n=41)

298

Discussion**Statement of principle findings**

Using a large general population cohort of women aged 65-84 years, this study has reported on the prevalence of rotator cuff pathology, the association of pathology to symptoms and uniquely the consequential impact on health services.

304

The prevalence of rotator cuff pathology has been well reported in the literature, and this general population study, supports previous findings. Prevalence was found to increase with every decile of age, and the relative risk of having a full thickness tear increased more than two-fold between the 65-69 and >80 age groups, suggesting a gradual decline of tendon tissue in response to aging. Overall, the prevalence of at least a unilateral full thickness tear was 22%. The dominant arm was 1.64 times likely to be affected, inferring that the presence of pathology may exist in shoulders with higher cumulative loading with functional tasks.

312

The relative risk of having symptomatic pathology (worsening OSS scores) increased with tear stage severity, though the severity of symptoms did not increase accordingly. Although larger tear size increased the likelihood of symptom presence, 48.4% of full-thickness rotator cuff tears remained asymptomatic.

317

The burden of musculoskeletal shoulder pain on health services is large, with 28.3% of individuals in this general population cohort having at some point sought medical advice for shoulder symptoms. This is the first study to look at the impact of rotator cuff tendinopathy and tears and the impact on the health services. Although on average only 50% of individuals with symptomatic rotator cuff tendinopathy will seek medical advice, the impact remains significant. Overall, almost 10% of individuals in the general population have sought medical advice for shoulder symptoms in the presence of a full-thickness tear, and almost 20% of the population for any tendon abnormality.

325

326

Strengths and weaknesses of this study

The major strength of this study is that it uses a large general population cohort, and therefore not subject to selection bias. The cohort was originally investigated with the primary focus of osteoporosis, and not shoulder symptoms, thus any continued participation is not driven by shoulder symptoms.

332

However, there are some potential limitations with the cohort used. Firstly, the cohort can only comment on associations in women aged between 65 and 84, but as previous studies have found no relationship between symptoms and age or sex^{23 30}, this will not bias the results. Potential survival bias is introduced by the cohort being in its 20th year, though, no known associations exist between shoulder pain and other medical co-morbidities. Furthermore, as the prime goal of the cohort was not

337

338 to investigate shoulder symptoms, this had no impact on continued study participation. Furthermore,
339 only 463/516 individuals that attended the year-20 study underwent a shoulder examination.

340

341 However, individuals that did were selected at random, and the age and BMI of the groups was not
342 statistically different to the full cohort. Bias arising from having two examiners was ameliorated by
343 two inter-observer reproducibility studies that demonstrated minimal effect of intra-observer analytic
344 bias. Furthermore, to demonstrate ultrasound-scanning accuracy a learning curve study was
345 undertaken a priori by both examiners, which demonstrated scanning accuracies comparable to those
346 quoted in the literature. Intra-observer studies also demonstrated good reproducibility. Reducing
347 analytic bias. Potential risk of overreporting pathology in symptomatic presentations is
348 acknowledged, though for pragmatic reasons, the physical assessment examiner was unblinded to the
349 OSS results.

350

351 The effect of tear size on symptom severity may have been underestimated in this study. The inability
352 to transform the complete data set, due to the skew of the OSS data, meant all asymptomatic
353 shoulders had to be removed and that we were only able to compare pain severity in the presence of a
354 tear compared to a painful normal shoulder. However, this may also reduce the background noise
355 from other painful conditions of the shoulder.

356

357 The definition of symptoms in previous studies varies widely with no consensus. The decision to use
358 the OSS was based upon its content, construct validity in relation to our research question, and
359 validation of use against other pain scores. Furthermore, dichotomisation of the scale at perfect vs.
360 non-perfect scores is not validated and may make results too sensitive. However, we ran a comparison
361 with 3-point change, as validated as clinically significant by the makers of the OSS, and there was no
362 statistical difference.

363

364 **Relationship to other studies**

365 This study has demonstrated similar prevalence figures to previous studies, but it is the first to use a
366 general population cohort that has been extensively characterised as representative of the western
367 world population.

368

369 Further studies have shown that the clinical presentation of rotator cuff tears varies and may or may
370 not be associated with symptoms^{17 22 23}. This general population cohort supports this with 48.4% of
371 full-thickness rotator cuff tears being asymptomatic. Prior to this, the only other population-based
372 study looking at symptom association with full-thickness tears was Yamamoto et al.³⁰ that
373 investigated symptom association with full-thickness tears using a mountain cohort in Japan. They
374 reported 34% of full-thickness tears to be symptomatic. However, unlike the current study, it was not
375 a general population cohort representative of western society. Furthermore, it was subject to selection
376 bias by removing any individuals with restricted shoulder movement or previous treatments.

377

378 Further studies have suggested that tear size affects the likelihood of symptoms. The current study
379 supports this with larger tears having a greater than 2-fold increase in relative risk of symptoms than
380 small tears^{17 22 23}. A previous study in the Washington series investigated by Yamaguchi et al²⁶,
381 reported development of symptoms in previously asymptomatic tendons in the context of a
382 contralateral symptomatic tear. However, this study was subject to selection bias as recruitment
383 occurred in a cohort actively being treated for contralateral symptomatic rotator cuff tears which may
384 have strengthened associations.

385

1
2
3 386 This is the first study that has looked at individuals as entities, rather than shoulders, and has
4 387 highlighted the effect the individual has on symptom presentation. It is also the first study to look at
5 388 the impact on health services.
6
7 389
8 390

9 391

391 **Meaning of the study and unanswered questions:**

10 392 This study has shown that although patient reported pain on the Oxford Shoulder Score is associated
11 393 with rotator cuff tendinopathy, it is not related to the extent of structural pathology identified on
12 394 ultrasound imaging. The likelihood of pain also appears to be strongly dependent upon the individual
13 395 rather than simply the pathology. Consequently, clinicians should rely less on imaging findings to
14 396 explain the cause and severity of shoulder pain presentations. Furthermore, other drivers of shoulder
15 397 pain should be considered (e.g. pain sensitisation), and treatment be targeted on symptom
16 398 management rather than solely interventions to improve tendon pathology.
17 399

20 400 Investigation into the impact of musculoskeletal shoulder pain on the healthcare system revealed that
21 401 28.8% of people in this general population cohort sought consultation with their GP for shoulder pain,
22 402 a third of whom had a full thickness tear, and a third with tendinopathy. This study highlights the
23 403 huge burden of shoulder pain on the healthcare system. Though, it does not demonstrate causality of
24 404 pain as is shown by the lack of symptoms in nearly half of cases and the lack of correlation with the
25 405 severity of pain and pathology. Nor does it show how the individual affects pain presentation.
26 406

28 407 This epidemiological study clearly demonstrates association but not causality and leaves unanswered
29 408 questions as to what additional factors contribute to pain. Particularly interesting is how individuals
30 409 may or may not have painful shoulders irrespective of the pathology. Further research into this could
31 410 provide alternative targets to treatment methods, and potentially reduce the cost of imaging modalities
32 411 and surgical interventions.
33 412

37 413 **Conclusion**

38 414 In conclusion, this general population study has demonstrated that full-thickness rotator cuff tears are
39 415 common affecting 22.1% of the over 60's and tendon abnormalities affecting 59.4%. Despite 41.7%
40 416 of individuals with a full-thickness tear (48.4% of all full-thickness tears) being asymptomatic, tendon
41 417 abnormalities and tears are associated with pain. The likelihood, but not severity of symptoms,
42 418 increases with greater structural damage.
43 419

45 420 This high prevalence and association of symptoms results in a significant impact on primary care
46 421 health services, with 28.3% of this population having presented to a GP with shoulder pain. Of these a
47 422 third had a full-thickness tear and a third had an abnormal but not torn tendon. Overall 8.9% of this
48 423 cohort had seen their general practitioner with shoulder pain and a full-thickness tear, and 18.8% had
49 424 seen their general practitioner with an abnormal or torn tendon.
50 425

52 **REFERENCES**

- 54 1. Vos T, Abajobir AA, Abate KH, et al. Global, regional, and national incidence, prevalence,
55 and years lived with disability for 328 diseases and injuries for 195 countries,
56 1990–2016: a systematic analysis for the Global Burden of Disease Study
57 2016. *The Lancet* 2017;390(10100):1211-59. doi: 10.1016/S0140-6736(17)32154-2
- 58 2. Urwin M, Symmons D, Allison T, et al. Estimating the burden of musculoskeletal disorders
59 in the community: the comparative prevalence of symptoms at different anatomical
60

- 1
2
3 sites, and the relation to social deprivation. *Annals of the rheumatic diseases*
4 1998;57(11):649-55. doi: 10.1136/ard.57.11.649 [published Online First: 1999/01/30]
- 5 3. Pope DP, Croft PR, Pritchard CM, et al. Prevalence of shoulder pain in the community: the
6 influence of case definition. *Annals of the rheumatic diseases* 1997;56(5):308-12. doi:
7 10.1136/ard.56.5.308
- 8 4. Bunker T. Rotator cuff disease. *Current Orthopaedics* 2002;16:223-33. doi:
9 10.1054/cuor.2002.0257
- 10 5. Meislin RJ, Sperling JW, Stitik TP. Persistent shoulder pain: epidemiology,
11 pathophysiology, and diagnosis. *American journal of orthopedics (Belle Mead, NJ)*
12 2005;34(12 Suppl):5-9. [published Online First: 2006/02/03]
- 13 6. Roquelaure Y, Ha C, Leclerc A, et al. Epidemiologic surveillance of upper-extremity
14 musculoskeletal disorders in the working population. *Arthritis Rheum*
15 2006;55(5):765-78. doi: 10.1002/art.22222 [published Online First: 2006/10/03]
- 16 7. Ng Man Sun S, Gillott E, Bhamra J, et al. Implant use for primary hip and knee
17 arthroplasty: are we getting it right first time? *J Arthroplasty* 2013;28(6):908-12. doi:
18 10.1016/j.arth.2012.11.012 [published Online First: 2013/03/20]
- 19 8. Hinsley H, Nicholls A, Daines M, et al. Classification of rotator cuff tendinopathy using
20 high definition ultrasound. *Muscles, ligaments and tendons journal* 2014;4(3):391-7.
21 [published Online First: 2014/12/10]
- 22 9. Teefey SA, Rubin DA, Middleton WD, et al. Detection and quantification of rotator cuff
23 tears. Comparison of ultrasonographic, magnetic resonance imaging, and arthroscopic
24 findings in seventy-one consecutive cases. *The Journal of bone and joint surgery*
25 *American volume* 2004;86(4):708-16. [published Online First: 2004/04/08]
- 26 10. de Jesus JO, Parker L, Frangos AJ, et al. Accuracy of MRI, MR arthrography, and
27 ultrasound in the diagnosis of rotator cuff tears: a meta-analysis. *AJR American*
28 *journal of roentgenology* 2009;192(6):1701-7. doi: 10.2214/ajr.08.1241 [published
29 Online First: 2009/05/22]
- 30 11. Naqvi GA, Jadaan M, Harrington P. Accuracy of ultrasonography and magnetic resonance
31 imaging for detection of full thickness rotator cuff tears. *Int J Shoulder Surg*
32 2009;3(4):94-97. doi: 10.4103/0973-6042.63218
- 33 12. Smith TO, Back T, Toms AP, et al. Diagnostic accuracy of ultrasound for rotator cuff
34 tears in adults: a systematic review and meta-analysis. *Clin Radiol* 2011;66(11):1036-
35 48. doi: 10.1016/j.crad.2011.05.007 [published Online First: 2011/07/09]
- 36 13. Dinnes J, Loveman E, McIntyre L, et al. The effectiveness of diagnostic tests for the
37 assessment of shoulder pain due to soft tissue disorders: a systematic review. *Health*
38 *Technol Assess* 2003;7(29):iii, 1-166. doi: 10.3310/hta7290 [published Online First:
39 2003/10/22]
- 40 14. Ottenheijm RP, Jansen MJ, Staal JB, et al. Accuracy of diagnostic ultrasound in patients
41 with suspected subacromial disorders: a systematic review and meta-analysis. *Arch*
42 *Phys Med Rehabil* 2010;91(10):1616-25. doi: 10.1016/j.apmr.2010.07.017 [published
43 Online First: 2010/09/30]
- 44 15. Fehring EV, Sun J, VanOeveren LS, et al. Full-thickness rotator cuff tear prevalence
45 and correlation with function and co-morbidities in patients sixty-five years and
46 older. *Journal of shoulder and elbow surgery / American Shoulder and Elbow*
47 *Surgeons [et al]* 2008;17(6):881-5. doi: 10.1016/j.jse.2008.05.039 [published Online
48 First: 2008/09/09]
- 49 16. Milgrom C, Schaffler M, Gilbert S, et al. Rotator-cuff changes in asymptomatic adults.
50 The effect of age, hand dominance and gender. *J Bone Joint Surg Br* 1995;77(2):296-
51 8. [published Online First: 1995/03/01]
- 52 17. Moosmayer S, Smith HJ, Tariq R, et al. Prevalence and characteristics of asymptomatic
53 tears of the rotator cuff: an ultrasonographic and clinical study. *J Bone Joint Surg Br*
54 2009;91(2):196-200. doi: 10.1302/0301-620x.91b2.21069 [published Online First:
55 2009/02/05]
- 56 18. Tempelhof S, Rupp S, Seil R. Age-related prevalence of rotator cuff tears in
57 asymptomatic shoulders. *Journal of shoulder and elbow surgery / American Shoulder*
58
59
60

- 1
2
3 *and Elbow Surgeons [et al]* 1999;8(4):296-9. doi: 10.1016/s1058-2746(99)90148-9
4 [published Online First: 1999/09/03]
- 5 19. Reilly P, Macleod I, Macfarlane R, et al. Dead men and radiologists don't lie: a review of
6 cadaveric and radiological studies of rotator cuff tear prevalence. *Ann R Coll Surg*
7 *Engl* 2006;88(2):116-21. doi: 10.1308/003588406x94968 [published Online First:
8 2006/03/23]
- 9 20. Yamamoto A, Takagishi K, Osawa T, et al. Prevalence and risk factors of a rotator cuff
10 tear in the general population. *Journal of shoulder and elbow surgery / American*
11 *Shoulder and Elbow Surgeons [et al]* 2010;19(1):116-20. doi:
12 10.1016/j.jse.2009.04.006 [published Online First: 2009/06/23]
- 13 21. Schibany N, Zehetgruber H, Kainberger F, et al. Rotator cuff tears in asymptomatic
14 individuals: a clinical and ultrasonographic screening study. *European journal of*
15 *radiology* 2004;51(3):263-8. doi: 10.1016/s0720-048x(03)00159-1 [published Online
16 First: 2004/08/06]
- 17 22. Yamaguchi K, Ditsios K, Middleton WD, et al. The demographic and morphological
18 features of rotator cuff disease. A comparison of asymptomatic and symptomatic
19 shoulders. *The Journal of bone and joint surgery American volume* 2006;88(8):1699-
20 704. doi: 10.2106/jbjs.E.00835 [published Online First: 2006/08/03]
- 21 23. Mall NA, Kim HM, Keener JD, et al. Symptomatic progression of asymptomatic rotator
22 cuff tears: a prospective study of clinical and sonographic variables. *The Journal of*
23 *bone and joint surgery American volume* 2010;92(16):2623-33. doi:
24 10.2106/jbjs.I.00506 [published Online First: 2010/11/19]
- 25 24. Needell SD, Zlatkin MB, Sher JS, et al. MR imaging of the rotator cuff: peritendinous and
26 bone abnormalities in an asymptomatic population. *AJR American journal of*
27 *roentgenology* 1996;166(4):863-7. doi: 10.2214/ajr.166.4.8610564 [published Online
28 First: 1996/04/01]
- 29 25. Sher JS, Uribe JW, Posada A, et al. Abnormal findings on magnetic resonance images of
30 asymptomatic shoulders. *The Journal of bone and joint surgery American volume*
31 1995;77(1):10-5. doi: 10.2106/00004623-199501000-00002 [published Online First:
32 1995/01/01]
- 33 26. Yamaguchi K, Tetro AM, Blam O, et al. Natural history of asymptomatic rotator cuff
34 tears: a longitudinal analysis of asymptomatic tears detected sonographically. *Journal*
35 *of shoulder and elbow surgery / American Shoulder and Elbow Surgeons [et al]*
36 2001;10(3):199-203. doi: 10.1067/mse.2001.113086 [published Online First:
37 2001/06/16]
- 38 27. Chandnani V, Ho C, Gerharter J, et al. MR findings in asymptomatic shoulders: a blind
39 analysis using symptomatic shoulders as controls. *Clin Imaging* 1992;16(1):25-30.
40 doi: 10.1016/0899-7071(92)90085-n [published Online First: 1992/01/01]
- 41 28. Minagawa H, Yamamoto N, Abe H, et al. Prevalence of symptomatic and asymptomatic
42 rotator cuff tears in the general population: From mass-screening in one village. *J*
43 *Orthop* 2013;10(1):8-12. doi: 10.1016/j.jor.2013.01.008 [published Online First:
44 2014/01/10]
- 45 29. Harris JD, Pedroza A, Jones GL. Predictors of pain and function in patients with
46 symptomatic, atraumatic full-thickness rotator cuff tears: a time-zero analysis of a
47 prospective patient cohort enrolled in a structured physical therapy program. *Am J*
48 *Sports Med* 2012;40(2):359-66. doi: 10.1177/0363546511426003 [published Online
49 First: 2011/11/19]
- 50 30. Yamamoto A, Takagishi K, Kobayashi T, et al. Factors involved in the presence of
51 symptoms associated with rotator cuff tears: a comparison of asymptomatic and
52 symptomatic rotator cuff tears in the general population. *Journal of shoulder and*
53 *elbow surgery / American Shoulder and Elbow Surgeons [et al]* 2011;20(7):1133-7.
54 doi: 10.1016/j.jse.2011.01.011 [published Online First: 2011/04/02]
- 55 31. Arden NK, Griffiths GO, Hart DJ, et al. The association between osteoarthritis and
56 osteoporotic fracture: the Chingford Study. *Br J Rheumatol* 1996;35(12):1299-304.
57 doi: 10.1093/rheumatology/35.12.1299 [published Online First: 1996/12/01]
- 58
59
60

- 1
2
3 32. Hart DJ, Mootoosamy I, Doyle DV, et al. The relationship between osteoarthritis and
4 osteoporosis in the general population: the Chingford Study. *Annals of the rheumatic*
5 *diseases* 1994;53(3):158-62. doi: 10.1136/ard.53.3.158 [published Online First:
6 1994/03/01]
7
8 33. Hart DJ, Spector TD. The relationship of obesity, fat distribution and osteoarthritis in
9 women in the general population: the Chingford Study. *J Rheumatol* 1993;20(2):331-
10 5. [published Online First: 1993/02/01]
11
12 34. Dawson J, Fitzpatrick R, Carr A. Questionnaire on the perceptions of patients about
13 shoulder surgery. *J Bone Joint Surg Br* 1996;78(4):593-600. [published Online First:
14 1996/07/01]
15
16 35. Dawson J, Rogers K, Fitzpatrick R, et al. The Oxford shoulder score revisited. *Archives of*
17 *orthopaedic and trauma surgery* 2009;129(1):119-23. doi: 10.1007/s00402-007-
18 0549-7 [published Online First: 2008/01/10]
19
20 36. Murphy RJ, Daines MT, Carr AJ, et al. An independent learning method for orthopaedic
21 surgeons performing shoulder ultrasound to identify full-thickness tears of the rotator
22 cuff. *The Journal of bone and joint surgery American volume* 2013;95(3):266-72.
23 doi: 10.2106/jbjs.K.00706 [published Online First: 2013/02/08]
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

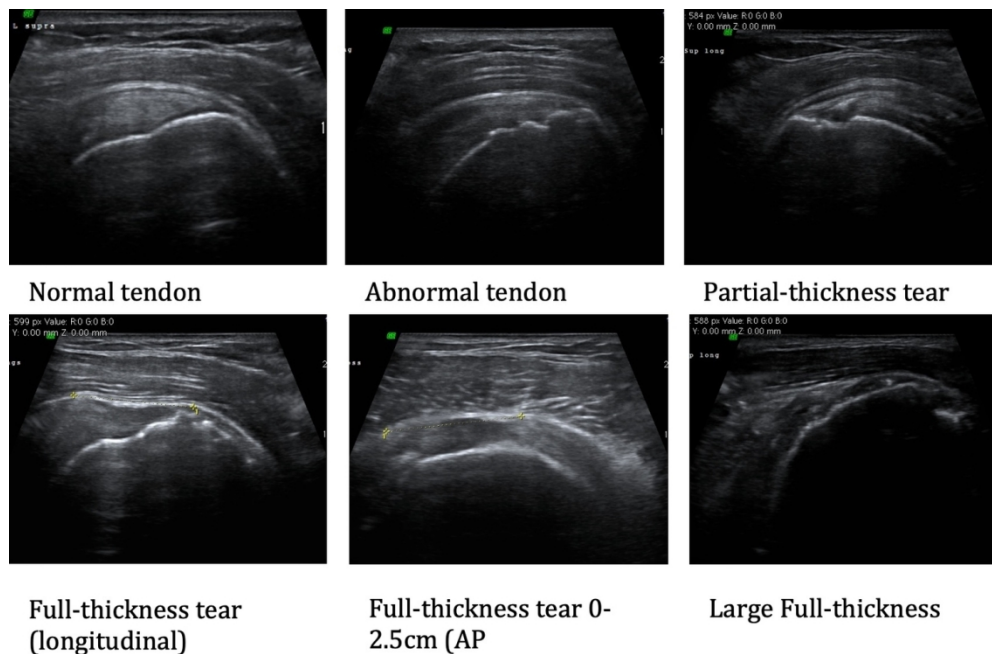


Figure 1: Ultrasound images

131x87mm (300 x 300 DPI)

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

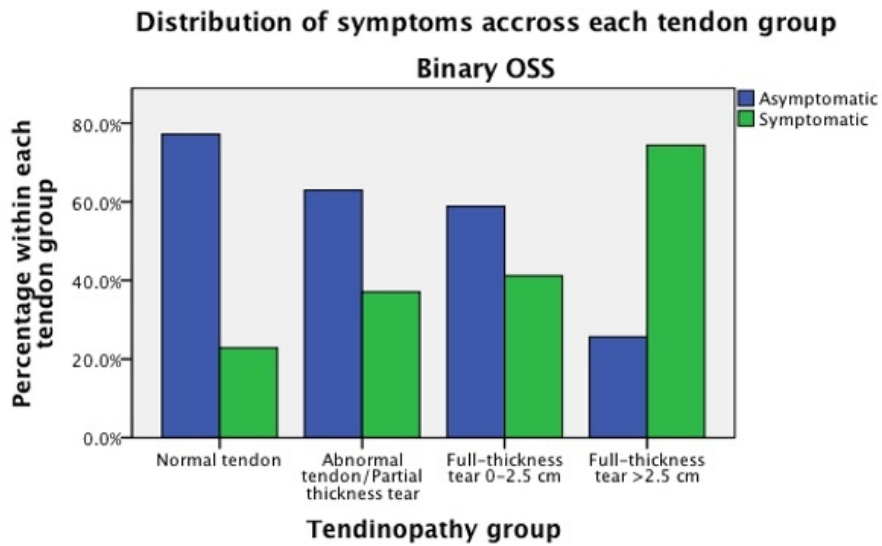


Figure 2. Distribution of symptoms across each tendon group

116x68mm (144 x 144 DPI)

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No.	Recommendation	Page No.	Relevant text from manuscript
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract (b) Provide in the abstract an informative and balanced summary of what was done and what was found	Page 1 Page 3	"large cross sectional observational study"
Introduction				
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Page 4	
Objectives	3	State specific objectives, including any prespecified hypotheses	page 4 lines 150-154	
Methods				
Study design	4	Present key elements of study design early in the paper	Page 4 - Design - from line 157	
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Page 4	
Participants	6	(a) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up <i>Case-control study</i> —Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls <i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants (b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed <i>Case-control study</i> —For matched studies, give matching criteria and the number of controls per case	Pages 4 and 5	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Page 5 - "Outcome measures"	
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Page 5	
Bias	9	Describe any efforts to address potential sources of bias	Page 10	"Strengths and weaknesses of this study"
Study size	10	Explain how the study size was arrived at	Page 4	

Continued on next page

Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Page 5-6 "Data analysis"
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding (b) Describe any methods used to examine subgroups and interactions (c) Explain how missing data were addressed (d) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed <i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed <i>Cross-sectional study</i> —If applicable, describe analytical methods taking account of sampling strategy (e) Describe any sensitivity analyses	SECTION 12 - See Page 5-6
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed (b) Give reasons for non-participation at each stage (c) Consider use of a flow diagram	Page 6 "464 individuals (928 shoulders) were included in the study (Table 1)."
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders (b) Indicate number of participants with missing data for each variable of interest (c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)	General cohort information described in the methods page 4
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time <i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure <i>Cross-sectional study</i> —Report numbers of outcome events or summary measures	Pages 6-9
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included (b) Report category boundaries when continuous variables were categorized (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	Tables 1-5, pages 6-9

Continued on next page

Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Not applicable
Discussion			
Key results	18	Summarise key results with reference to study objectives	Page 9
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	Page 10 "Strengths and limitations of the study"
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Page 11 "Meaning of the study and unanswered questions"
Generalisability	21	Discuss the generalisability (external validity) of the study results	End of Page 11 - "This epidemiological study clearly demonstrates association but not causality..."
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Page 2 "role of the funding body"

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

Prevalence of rotator cuff tendon tears and symptoms in a Chingford general population cohort, and the resultant impact on United Kingdom health services: A cross-sectional observational study.

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2021-059175.R1
Article Type:	Original research
Date Submitted by the Author:	16-Mar-2022
Complete List of Authors:	Hinsley, Hannah; University of Oxford Nuffield Department of Orthopaedics Rheumatology and Musculoskeletal Sciences Ganderton, Charlotte; Swinburne University of Technology Faculty of Health Arts and Design, Nursing and Allied Health Arden, Nigel; University of Oxford , University of Oxford Nuffield Department of Orthopaedics Rheumatology and Musculoskeletal Sciences, Carr, Andrew; University of Oxford, University of Oxford Nuffield Department of Orthopaedics Rheumatology and Musculoskeletal Sciences,
Primary Subject Heading:	Public health
Secondary Subject Heading:	Diagnostics, Evidence based practice, Sports and exercise medicine
Keywords:	Shoulder < ORTHOPAEDIC & TRAUMA SURGERY, Ultrasonography < OBSTETRICS, Musculoskeletal disorders < ORTHOPAEDIC & TRAUMA SURGERY, Diagnostic radiology < RADIOLOGY & IMAGING

SCHOLARONE™
Manuscripts



I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our [licence](#).

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which [Creative Commons](#) licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

1
2
3 1 **Prevalence of rotator cuff tendon tears and symptoms in a Chingford general population**
4 2 **cohort, and the resultant impact on United Kingdom health services: A cross-sectional**
5 3 **observational study.**
6 4

7 4
8 5 Hannah Hinsley^{1*}, Charlotte Ganderton², Nigel Arden^{1^}, Andrew Carr^{1^}

9 6 ¹ The Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, University
10 7 of Oxford, Oxford, United Kingdom
11

12 8 ² Department of Health Sciences and Biostatistics, Faculty of Health Arts and Design, Swinburne
13 9 University of Technology, Hawthorn, Victoria, Australia
14

15 10
16 11 **Author information:**

17 12 Dr Hannah Hinsley; Orthopaedic Surgeon, ARUK orthopaedic clinical research fellow, The Nuffield
18 13 Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, University of Oxford,
19 14 United Kingdom; hannah.hinsley@nhs.net
20 15

21 16 [^]Professor Nigel Arden; Lead of Musculoskeletal Epidemiology, Deputy Director Centre for Sport,
22 17 Exercise & Osteoarthritis Research Versus Arthritis and Fellow at the Lady Margaret Hall at The
23 18 Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, University of
24 19 Oxford, United Kingdom; nigel.arden@ndorms.ox.ac.uk
25 20

26 21 Dr Charlotte Ganderton, Physiotherapist and Lecturer at the Department of Health Sciences and
27 22 Biostatistics, Faculty of Health Arts and Design, Swinburne University of Technology, Hawthorn,
28 23 Victoria, Australia, cganderton@swin.edu.au
29 24

30 25 [^]Professor Andrew Carr, Professor of Orthopaedics at The Nuffield Department of Orthopaedics,
31 26 Rheumatology and Musculoskeletal Sciences, University of Oxford, United Kingdom; Director of the
32 27 Botnar Research Centre; andrew.carr@ndorms.ox.ac.uk
33 28

34 29 *Corresponding author: Dr Hannah Hinsley

35 30 Contact address: Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences,
36 31 NIHR Biomedical Research Unit, Botnar Research Centre, University of Oxford, Nuffield
37 32 Orthopaedic Centre, Windmill Road, OX3-7LD Oxford, United Kingdom
38 33

39 34 [^]Senior co-authors
40 35
41 36
42 37
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

1
2
3 38 **Contributors:** HH, NA, AC were responsible for planning, conducting, and reporting the work
4 39 described in the article. HH and CG drafted the manuscript. All authors approved the final version of
5 40 the article. HH, NA and AC had access to all the data in the study and can take responsibility for the
6 41 integrity of the data and the accuracy of the data analysis. HH is guarantor. The corresponding author
7 42 attests that all listed authors meet authorship criteria and that no others meeting the criteria have been
8 43 omitted. All authors fully acknowledge the contribution of the patients that participated in this study.
9 44 No authors are employees of the National Institutes of Health.

10
11
12
13 45 **Transparency Statement:** The lead author (the manuscript's guarantor) affirms that the manuscript
14 46 is an honest, accurate, and transparent account of the study being reported; that no important aspects
15 47 of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant,
16 48 registered) have been explained.

17 49
18
19 50 **Role of the funding source:** Arthritis Research United Kingdom awarded the project £190,361.00 to
20 51 cover costs to completion. Researchers were independent from the funding body. All authors, external
21 52 and internal, had full access to all the data (including statistical reports and tables) in the study and
22 53 can take responsibility for the integrity of the data and the accuracy of the data analysis.

23 54
24 55 **Competing interests:** No competing interests

25 56
26 57 **Ethics approval:** Outer North East London Research Ethics Committee (formerly Barking and
27 58 Havering and Waltham Forest RECs), LREC (R&WF) reference ID = 96.

28 59 29 60 **Patient and public involvement**

30 61 We would like to thank all the participants of the Chingford Women Study for their time.
31 62 We would also like to thank Mrs Maxine Daniels and Dr Alan Hakim for their time and dedication,
32 63 and both Mr Alex Nichols and Mr Michael Daines for their assistance with data collection and Dr
33 64 Gemma Wallis for her assistance with data analysis.

34 65 35 66 **Acknowledgement**

36 67 Thank you to Dr Gemma Wallis, Statistician, for reviewing statistical analysis processes used in this
37 68 study.

38 69
39 70 **Data sharing:** For information about the Chingford 1000 Women Study,
40 71 email chingford@ndorms.ox.ac.uk.

41 72
42 73 **Dissemination to participants and related patient and public communities:** We will disseminate
43 74 our findings to patient organisations and media outlets.

44 75
45 76 **Provenance and peer review:** Not commissioned; peer reviewed at Orthopaedic meetings.
46 77

78 Structured Abstract

80 Objectives:

81 To define the population prevalence of rotator cuff tears and test their association with pain and
82 function loss; determine if severity symptom correlates with tear stage severity, and quantify the
83 impact of symptomatic rotator cuff tears on primary health care services, in a general population
84 cohort of women.

86 Design:

87 Cross sectional observational study.

89 Participants:

90 Individuals were part of the Chingford 1000 women cohort, a 20-year-old longitudinal population
91 study comprising 1003 women aged between 64 and 87, and representative of the population of the
92 UK.

94 Main outcome measures:

95 Rotator cuff pathology prevalence on ultrasound, shoulder symptoms using the Oxford shoulder
96 score, and resultant number of GP consultations.

98 Results:

99 The population prevalence of full-thickness tears was 22.2%, which increased with age ($p=0.004$),
100 and whether it was the dominant arm (RR 1.64, OR 1.58, 95% CI 1.07-2.33, $p=0.021$).

101 Although 48.4% of full-thickness tears were asymptomatic there was an association between rotator
102 cuff tears and patient reported symptoms. Individuals with at least one full-thickness tear were 1.97
103 times more likely, than those with bilateral normal tendons (OR 3.53, 95%CI 2.00-5.61, $p<0.001$), to
104 have symptoms. Severity of symptoms was not related to the severity of the pathology until tears are
105 $>2.5\text{cm}$ ($p=0.009$).

106 In the cohort 8.9% had seen their GP with shoulder pain and a full-thickness rotator cuff tear, 18.8%
107 with an abnormality and 29.3% overall.

111 Conclusion:

112 Rotator cuff tears are common, and primary care services are heavily impacted. As 50% of tears
113 remain asymptomatic, future research may investigate the cause of pain and whether different
114 treatment modalities, aside from addressing the pathology, need further investigation.

116 Trial Registration:

117 The local ethics committee approved the study (Outer North East London Research Ethics Committee
118 (formerly Barking and Havering and Waltham Forest RECs), LREC (R&WF) reference ID = 96).

120 Strengths and limitations of this study:

- 121 • Pain on the Oxford Shoulder Score is associated with the presence of rotator cuff tendon pain,
122 but not the extent of structural pathology identified on ultrasound imaging.
- 123 • Rotator cuff pathology and associated symptoms pose a large burden on the healthcare system
124 with 28.8% of people seeking GP consultation for their shoulder pain.
- 125 • This epidemiological study demonstrates association but not causality and leaves unanswered
126 questions as to what additional factors contribute to shoulder pain.

127 **Introduction**

128 **Background**

129 Musculoskeletal pain is one of the most common sources of disability in the Western world¹. The
130 shoulder is the third most common site of musculoskeletal disease², with an estimated 20% of the
131 population reporting pain at any given time³. Pain related to rotator cuff tears are estimated to account
132 for 30-40% of these shoulder complaints⁴, causing high levels of disability and associated healthcare
133 costs⁵⁻⁷. High-definition ultrasound is the current gold standard for the detection of full-thickness
134 tears, and is a valid tool to detect an abnormal tendon enthesis⁸, but has poorer accuracy to detect
135 partial-thickness tears⁸⁻¹⁴. Full thickness tears are recognised to be common and associated with
136 increasing age¹⁵⁻¹⁸, however prevalence in symptomatic and asymptomatic shoulders varies widely
137 across cadaveric¹⁹, radiological¹⁹ and retrospective cohort studies^{16-18 20-28}. Furthermore, the presence
138 of selection bias in studies undertaken in rotator cuff tendon tears¹⁶⁻²⁸, has meant population-based
139 studies available, are not representative of Western demographics. Thus, research in this area may
140 lead to a better understanding of the natural history of rotator cuff tears.

141
142 Clinical manifestations of rotator cuff tears are varied^{15 17 22 26 28}, and detection of pathology and its
143 relationship to clinical symptoms is not well established. Many tears are asymptomatic but are
144 thought to be a risk of developing symptoms with time²⁶. Although larger tears are more likely to be
145 painful, there is also no evidence to suggest that they have a greater severity of symptoms than
146 smaller tears²⁹. One population cohort from a mountainous region has suggested that only a third of
147 full-thickness tears were painful, of which symptoms were more prevalent in the dominant arm³⁰.
148 However, all studies investigating symptom association have looked at isolated shoulders, and have
149 not considered that the individual, has two shoulders. It is therefore plausible that there may be the
150 presence of other physical or psychological factors unique to the individual, rather than the specific
151 shoulder, that may have an influence on symptom presentation, rather than solely the underlying
152 pathology. To date, no study has explored the association between rotator cuff tears, pain and
153 functional loss in a general population cohort, or how these impact on a health service.

155 **Objectives**

156 This study aims to: (i) describe the population prevalence of different stages of rotator cuff tear in a
157 general population cohort of women; (ii) determine what proportion of rotator cuff tears are
158 symptomatic, and whether the severity of symptoms correlates with tear stage severity; (iii) identify
159 individual influences on the likelihood of symptoms and (iv) quantify the impact of symptomatic
160 rotator cuff tears on primary health care services.

163 **Methods**

164 *Study Design, Setting and Participants (including study size)*

165 Participants in this cross-sectional observational study were involved in the larger Chingford 1000
166 women study. This is an ethically approved well described prospective population-based longitudinal
167 study of osteoarthritis and osteoporosis comprising 1003 white Caucasian women, derived from the
168 register of a large general practice in Chingford, North London³¹⁻³³. The cohort was recruited in 1989
169 where the women were aged 44-67. They have been characterised as representative of women in the
170 UK general population with respect to weight, height, and smoking characteristics. The cohort has
171 been subsequently listed by the National Institute for Health Research as an important
172 epidemiological recourse. This study took place at the Chingford 20 year follow up visit where 516 of
173 the original 1003 cohort attended (158 women had died, 111 were unable to attend, 218 had moved

away or been lost to follow up). A musculoskeletal assessment, including the Oxford shoulder score, and shoulder ultrasound examination was performed on both shoulders (left and right) in 463 women (Out of the 515, 52 attended but did not have a shoulder assessment due to lack of assessor, and 1 did not complete an Oxford shoulder score). The local ethics committee approved the study and consent was obtained from each woman (Outer North East London Research Ethics Committee (formerly Barking and Havering and Waltham Forest RECs), LREC (R&WF) reference ID = 96).

Variables and data sources:

Participant characteristics of age, height, weight, hand dominance, and a self-reported musculoskeletal questionnaire filled out a priori (including the Oxford Shoulder Score^{34 35}, body chart and questions regarding previous pain, treatments and whether medical advice has been sought), were all collected at baseline. A musculoskeletal ultrasound assessment on bilateral shoulders was then undertaken using a fixed SOPP (standard operating procedure protocol).

The ultrasound examination of the 464 women was completed by two orthopaedic assessors and performed using a GE voluson i-portable ultrasound machine with a 10-16MHz linear probe. Ultrasound training and appropriate validation studies³⁶ were completed as recommended by the BESS focus group - 343 individuals were scanned by assessor 1 and 121 individuals by assessor two. Appropriate inter and intra-rater reliability studies were performed and showed high reproducibility (weighted kappa 0.92 $p < 0.001$) and no difference in reporting trends ($p = 0.08$). The ultrasound protocol was derived according to the recommendations of the Nuffield Orthopaedic Centre Musculoskeletal radiology department. Tendons were classified into one of four working groups based upon ultrasound measurements as validated by Hinsley et al.⁸: normal tendon; abnormal tendon and partial thickness tear; single tendon full-thickness tears (0-2.5cm) and multi-tendon full-thickness tears (> 2.5 cm) (Figure 1).

Figure 1: Tendon classification on ultrasound

Figure 1 legend: (i) normal tendon: normal homogenous appearance throughout with no abnormality at the enthesis; (ii) abnormal tendon: loss of homogenous appearance and abnormal ragged enthesis +/- enlarged fluid-filled bursa or partial thickness tear; (iii) full thickness tear (0-2.5cm): lucent patch through the full thickness of the tendon with tear size defined as its width in the sagittal plane (iv) full-thickness tears (> 2.5 cm): Evidence of large defect or no evidence of tendon tissue present.

Quantitative variables and Statistical methods

All statistics were performed using IBM SPSS Statistics version 22 (IBM, Armonk, NY, USA). Age, BMI, hand dominance, and symptom presence were compared across the four different tendon pathology groups. Wilcoxon rank sum test, one-way ANOVA, and chi-squared tests were used for non-normal, normal and categorical data respectively.

Population prevalence of full-thickness tears was defined as having at least one unilateral full-thickness tear. Population prevalence of tendon abnormalities was defined as having at least a unilateral tendon abnormality ranging from abnormal enthesis to a full thickness tear. This was calculated by summing the percentage with unilateral tears and the percentage with bilateral tears for each age group.

Symptoms were defined using the Oxford shoulder score^{34 35}. This was chosen for what the authors believed represented the best content and construct validity as applicable to the study as it covers a range of symptoms (both relating to pain and function) over a 4-week time period, and also allows

discriminate ability. Binary symptoms were defined by dichotomising the Oxford shoulder score^{34 35} where, any non-perfect score ($\leq 47/48$) was classified as symptomatic. The cut off at 47 was used to determine symptoms as we were not looking for significant changes, rather, the ability to detect any individual who was unable to perform an activity to the full, or who has pain at any given time. This showed good correlation with binary pain questions and the NRS and was not statistically different to the results using a 3-point gap. Where questions are pain specific, the four pain specific questions of the OSS were used as a sub-scale. In symptomatic participants, the full OSS scale, scored on a 0-48 point scale, was used to define symptom severity. A Chi² test was used to determine any difference between tendon pathology groups. Multivariate binary logistic regression was used to adjust for the potential confounders age, BMI and hand dominance determined a priori. To account for a high positive skew of the OSS data when determining symptom severity, all asymptomatic shoulders were removed, and a logarithmic transformation of the inverse OSS was used to create a normal distribution. Symptom severity in symptomatic shoulders was compared across tendon pathology groups using a 1-way ANOVA. Multivariate linear regression was used to adjust for potential confounders age, and hand dominance determined a priori.

236 Results

237 Participants and descriptive data

238 464 individuals (928 shoulders) were included in the study (Table 1). The distribution of age across
239 each tendon pathology group was significantly different ($p<0.001$), with age increasing in accordance
240 with tear severity. There was a statistical difference in the proportion of dominant and non-dominant
241 arms in each tendon pathology group ($p=0.033$), with there being significantly more non-dominant
242 arms in the normal tendon group ($p=0.010$), and significantly more dominant arms in those with full-
243 thickness tears ($p=0.026$). There were no between-group differences in BMI ($p=0.080$).

244
245 Table 1. Demographics of shoulders included in the study

	Frequency	%	Median age	Mean BMI	Dominant arm (%)
Normal	510	55.0%	70	27.5	46.1%
Abnormal/ Partial tear	294	31.7%	73	28.0	52.7%
Full-thickness tears (0-2.5cm)	85	9.2%	74	27.9	58.8%
Full-thickness tears (>2.5cm)	39	4.2%	74	29.6	61.5%
All	928	100%	71	27.8	50%

246 Outcome data and main results

247 Prevalence of rotator cuff tendon pathology

248 The population prevalence of having at least one full-thickness tear was 22.2% (4.5% bilateral). For
249 age groups 60-69, 70-79 and 80-89 these were 14.9%; 25.9% and 29% respectively, and bilateral tears
250 2.3%; 5.9% and 5.8% respectively. The difference in prevalence between age groups was statistically
251 different ($p<0.001$).

252
253 The population prevalence of having at least a unilateral tendon pathology or tear was 59.5% (30.6%
254 bilateral). For age groups 60-69, 70-79 and 80-89 these were 51.5%; 61.8% and 72.5% respectively,
255 and bilateral tears 24.6%; 32.3% and 40.6% respectively. The difference in population prevalence
256 between age groups was statistically significant ($p<0.001$).

257

Table 2 shows the prevalence of rotator cuff tendinopathy in the dominant and non-dominant arms in age deciles. The distribution of tendinopathy differed between age groups (Dominant arm $p=0.002$; non-dominant arm $p=0.037$) with more pathology found in older age groups, and in the dominant compared to non-dominant arms ($p=0.004$). There was no difference in prevalence according to BMI group. The relative risk of full-thickness tear was 1.64 (OR 1.580, 95%CI 1.073-2.326, $p=0.021$) in the dominant compared to non-dominant arm. For those aged 70-79 it was 2.072 (OR 2.026, 95%CI 1.286-3.190, $p=0.002$), and aged 80-89 was 2.293 (OR 2.256, 95%CI 1.264-4.027, $p=0.006$), compared to those aged 60-69.

Table 2. Prevalence of rotator cuff tendon pathology according to age decile and arm dominance

	Age Group							
	60-69 (n=175)		70-79 (n=220)		80-89 (n=69)		Total (n=464)	
	Count	%	Count	%	Count	%	Count	%
Dominant arm								
Normal tendon	102	58.3%	111	50.5%	22	31.9%	235	50.6%
Abnormal tendon/Partial thickness tear	54	30.9%	67	30.5%	34	49.3%	155	33.4%
Full-thickness tear 0-2.5 cm	14	8.0%	27	12.3%	9	13.0%	50	10.8%
Full-thickness tear >2.5 cm	5	2.9%	15	6.8%	4	5.8%	24	5.2%
Non-dominant arm								
Normal tendon	115	65.7%	122	55.5%	38	55.1%	275	59.3%
Abnormal tendon/Partial thickness tear	49	28.0%	70	31.8%	20	29.0%	139	30.0%
Full-thickness tear 0-2.5 cm	10	5.7%	18	8.2%	7	10.1%	35	7.5%
Full-thickness tear >2.5 cm	1	0.6%	10	4.5%	4	5.8%	15	3.2%

268

269 Association of symptoms (all shoulders)

270 An analysis of symptom association was completed in 926 shoulders (463/464 participants due to loss
271 of one questionnaire). There were 289 (31.2%) symptomatic shoulders according to a dichotomised
272 OSS. The presence of symptoms was statistically significant between tendon groups ($p<0.001$);
273 51.6% of all full-thickness tears were symptomatic. There was no difference in age, BMI or arm
274 dominance between symptomatic or asymptomatic shoulders. The relative risks of having symptoms
275 compared to those with a reported normal tendon were as follows: Abnormal/Partial tears 1.969 (OR
276 1.991, 95%CI 1.454-2.727); full-thickness tears 0-2.5cm 2.203 (OR 2.366, 95%CI 1.465-3.891); and
277 full-thickness tears >2.5cm 4.718 (OR 9.800, 95%CI 4.638-20.705). All were significant ($p<0.001$)
278 with the model correctly predicting 71% of symptom outcomes correctly. The distribution of
279 symptoms across each tendon group is shown in Figure 2.

280

281 Figure 2. Distribution of symptoms across each tendon group

282 Symptom severity

283 For the 289 symptomatic shoulders the full OSS was reported (Table 3). Median age was significantly
284 different between groups ($p=0.047$), with age increasing with tear stage severity. No statistically
285 significant between-group differences in BMI were identified, nor any within-group differences for
286 arm dominance.

287

288 Table 3. Symptom severity demographics

	N	Median age	Mean BMI	Dominant arm (%)
Normal	116	70	28.3	46.6%
Abnormal/Partial tear	109	73	28.4	54.1%
Full-thickness tears 0-2.5cm	35	72	28.1	62.9%
Full-thickness tears >2.5cm	29	73	30.3	58.6%
All	289	71	28.5	50%

289

290

291

292

293

294

295

296

297

298

299

300

301

302

303

304

305

306

307

308

309

310

311

312

313

314

315

316

317

318

319

320

321

322

323

324

325

326

327

328

329

330

The mean OSS for symptomatic shoulders was 41.8. For normal tendons this was 42.5, abnormal tendons, 42.1; full-thickness tears (0-2.5cm), 40.2; and full-thickness tears (>2.5cm), 38.4. There was a statistical difference between the groups (1 way ANOVA $p=0.030$). Linear regression analysis after adjustment for age, BMI, and hand dominance (no interactions identified), showed that the only significant difference in OSS scores was between normal tendons (mean OSS 42.5) and large full-thickness tears (OSS 38.3), $p=0.009$, power 0.75 (overall model $p=0.007$, power 0.892).

Association of symptoms (individuals)

Table 4 shows the relationship between the individual, presence of full-thickness rotator cuff tear and the likelihood of symptoms. A clustering effect of bilateral symptoms or lack thereof is present, irrespective of the underlying pathology. After adjustment for age and BMI, compared to those with bilaterally normal shoulders the relative risk of having at least one symptomatic shoulder in the presence of a full thickness rotator cuff tear is 1.49 (OR 1.867, 95%CI 1.200-2.904), and 1.97 (OR 3.352, 95%CI 2.003-5.609) in the presence of at least a unilateral abnormality or cuff tear.

Table 4. Distribution of individual shoulder symptoms according to the presence of full-thickness tears

	No Symptoms	Unilateral Symptoms	Bilateral Symptoms	Total
Bilateral No FTT	226	71	63	360
Unilateral FTT	33	25	24	82
Bilateral FTT	10	3	8	21
Total	269	99	95	463

307

308

309

310

311

312

313

314

315

316

317

318

319

320

321

322

323

324

325

326

Shoulder pain and use of primary care health services

Table 5 shows the proportion of individuals with shoulder pain, past or present, seeking medical advice. The likelihood of seeking medical attention for shoulder pain was statistically different between each pathology group (Chi² test $p=0.005$) reflecting the increasing likelihood of pain. However, of those with pain the likelihood of seeking medical attention was not statistically different between groups (Chi² test $p=0.179$). Overall, 28.3% (131/463) of all individuals had at some stage seen their GP for shoulder pain. In this cohort, 8.9% (41/463) had seen their GP with shoulder pain and a full-thickness tendon tear and 18.8% (87/463) had seen their GP with an abnormal tendon or full thickness tear.

A multivariable regression model using all individuals was used to predict the likelihood of attending a GP for shoulder pain. The presence of at least one full-thickness tear had a relative risk of 1.63 (OR 2.179, 95%CI 1.282-3.703) compared to those with normal tendons of attending the GP. There was

no statistical difference in relative risk of those with any tendon abnormality compared to those with bilaterally normal shoulders.

Table 5. Proportion of individuals seeking medical advice

	Present symptoms (either shoulder)		Past or Present symptoms (either shoulder)		All individuals % seen GP
	%	% seen GP	%	% seen GP	
All individuals (n=463)	41.9 (n=194)	44.8 (n=87)	55.7 (n=258)	50.8 (n=131)	28.3 (n=131)
Bilaterally normal tendons (n=187)	29.9 (n=56)	41.1 (n=23)	48.1 (n=90)	48.9 (n=44)	23.5 (n=44)
At least one abnormality (no tear) (n=173)	45.1 (n=78)	41.0 (n=32)	57.2 (n=99)	46.5 (n=46)	26.6 (n=46)
At least one full- thickness tear (n=103)	58.3 (n=60)	53.3 (n=32)	67.0 (n=69)	59.4 (n=41)	39.8 (n=41)

Discussion

Key results

Using a large general population cohort of women aged 65-84 years, this study has reported on the prevalence of rotator cuff pathology, the association of pathology to symptoms and uniquely the consequential impact on health services.

The prevalence of rotator cuff pathology has been well reported in the literature, and this general population study, supports previous findings. Prevalence was found to increase with every decile of age, and the relative risk of having a full thickness tear increased more than two-fold between the 65-69 and >80 age groups, suggesting age related change¹⁸. Overall, the prevalence of at least a unilateral full thickness tear was 22%. The dominant arm was 1.64 times likely to be affected, inferring that the presence of pathology may exist in shoulders with higher cumulative loading.

The relative risk of having symptomatic pathology (worsening OSS scores) increased with tear stage severity, though the severity of symptoms did not increase accordingly. Although larger tear size increased the likelihood of symptom presence, 48.4% of full-thickness rotator cuff tears remained asymptomatic.

The burden of musculoskeletal shoulder pain on health services is large, with 28.3% of individuals in this general population cohort having at some point sought medical advice for shoulder symptoms. This is the first study to look at the impact of rotator cuff pathology on the impact on the health services. Although on average only 50% of individuals with symptomatic rotator cuff tendon pathology (tendinopathy) will seek medical advice, the impact remains significant. Overall, almost 10% of individuals in the general population have sought medical advice for shoulder symptoms in the presence of a full-thickness tear, and almost 20% of the population for any tendon abnormality.

1
2
3 350 The major strength of this study is that it uses a large general population cohort, and therefore not
4 351 subject to selection bias. The cohort was originally investigated with the primary focus of
5 352 osteoporosis, and not shoulder symptoms, thus any continued participation is not driven by shoulder
6 353 symptoms.
7 354

9 355 **Limitations (including bias)**

10 356 The cohort can only comment on associations in women aged between 65 and 84, but as previous
11 357 studies have found no relationship between symptoms and age or sex^{23,30}, this will not bias the
12 358 results. Potential survival bias is introduced by the cohort being in its 20th year. If a greater proportion
13 359 of individuals with pathology were lost to follow up this may cause us to under-estimate any
14 360 association, however, no known associations exist in the literature between rotator cuff tears and other
15 361 medical co-morbidities. Furthermore, as the prime goal of the cohort was not to investigate shoulder
16 362 symptoms, this had no impact on continued study participation. Furthermore, only 463/516
17 363 individuals that attended the year-20 study underwent a shoulder examination due to lack of an
18 364 examiner being present at these follow up appointments. However, the age and BMI of the groups
19 365 was not statistically different to the full cohort.
20 366

21 367 Bias arising from having two examiners was ameliorated by two inter-observer reproducibility studies
22 368 that demonstrated minimal effect of inter-observer analytic bias. Furthermore, to demonstrate
23 369 ultrasound-scanning accuracy a learning curve study was undertaken a priori by both examiners,
24 370 which demonstrated scanning accuracies comparable to those quoted in the literature. Inter-observer
25 371 studies also demonstrated good reproducibility reducing analytic bias. Potential risk of overreporting
26 372 pathology in symptomatic presentations is acknowledged as the assessor (ultrasonographer) was
27 373 unblinded to the OSS result, as for pragmatic reasons due to lack of assessors, both assessments were
28 374 carried out by the same individual. To overcome this, a small intra-observer study was completed,
29 375 and an additional ultrasound scan was performed on 18 willing participants. The examiner was blind
30 376 to all previous results and shoulder scores. Overall agreement gave a weighted kappa score of 0.915
31 377 ($p < 0.001$).
32 378

33 379 The effect of tear size on symptom severity may have been underestimated in this study. The inability
34 380 to transform the complete data set due to the skew of the OSS data, meant all asymptomatic shoulders
35 381 had to be removed. Pain severity in the presence of a tear was then compared to a pain severity in a
36 382 normal (no tendon pathology) shoulder. We recognise that there may be many causes of shoulder pain
37 383 (e.g., rheumatological causes) and therefore referencing against all causes of painful shoulder may
38 384 represent the contribution of rotator cuff tear to the symptoms.
39 385

40 386 The definition of symptoms in previous studies varies widely with no consensus. The decision to use
41 387 the OSS was based upon its content, construct validity in relation to our research question, and
42 388 validation of use against other pain scores. Furthermore, dichotomisation of the scale at perfect vs.
43 389 non-perfect scores is not validated and may make results too sensitive. However, we ran a comparison
44 390 with 3-point change, as validated as clinically significant by the makers of the OSS, and there was no
45 391 statistical difference.
46 392

47 393 *Relationship to other studies*

48 394 This study has demonstrated similar prevalence figures to previous studies, but it is the first to use a
49 395 general population cohort that has been extensively characterised as representative of the western
50 396 world population.
51 397

1
2
3 398 Further studies have shown that the clinical presentation of rotator cuff tears varies and may or may
4 399 not be associated with symptoms^{17 22 23}. This general population cohort supports this with 48.4% of
5 400 full-thickness rotator cuff tears being asymptomatic. Prior to this, the only other population-based
6 401 study looking at symptom association with full-thickness tears was Yamamoto et al.³⁰ that
7 402 investigated symptom association with full-thickness tears using a mountain cohort in Japan. They
8 403 reported 34% of full-thickness tears to be symptomatic. However, unlike the current study, it was not
9 404 a general population cohort representative of western society. Furthermore, it was subject to selection
10 405 bias by removing any individuals with restricted shoulder movement or previous treatments.
11
12 406

13
14 407 Further studies have suggested that tear size affects the likelihood of symptoms. The current study
15 408 supports this with larger tears having a greater than 2-fold increase in relative risk of symptoms than
16 409 small tears^{17 22 23}. A previous study in the Washington series investigated by Yamaguchi et al²⁶,
17 410 reported development of symptoms in previously asymptomatic tendons in the context of a
18 411 contralateral symptomatic tear. However, this study was subject to selection bias as recruitment
19 412 occurred in a cohort actively being treated for contralateral symptomatic rotator cuff tears which may
20 413 have strengthened associations.
21
22 414

23
24 415 This is the first study that has looked at individuals as entities, rather than shoulders, and has
25 416 highlighted the effect the individual has on symptom presentation, which could include physical and
26 417 psychological factors unique to that individual – not solely the presence of tendon pathology on
27 418 imaging. It is also the first study to look at the impact on health services.
28
29 419

30 420

31 421 **Interpretation**

32 422 This study has shown that although patient reported pain on the Oxford Shoulder Score is associated
33 423 with rotator cuff tendon pathology, it is not related to the severity of structural pathology identified on
34 424 ultrasound imaging. The likelihood of pain also appears to be strongly dependent upon the individual
35 425 rather than simply the pathology. Consequently, clinicians should rely less on imaging findings to
36 426 explain the cause and severity of shoulder pain presentations. Furthermore, other drivers of shoulder
37 427 pain should be considered (e.g. pain sensitisation), and treatment be targeted on symptom
38 428 management rather than solely interventions to improve tendon pathology.
39
40 429

41
42 430 Investigation into the impact of musculoskeletal shoulder pain on the healthcare system revealed that
43 431 28.8% of people in this general population cohort sought consultation with their GP for shoulder pain,
44 432 a third of whom had a full thickness tear, and a third with at least one abnormality (no tear). This
45 433 study highlights the huge burden of shoulder pain on the healthcare system. Though, it does not
46 434 demonstrate causality of pain as is shown by the lack of symptoms in nearly half of cases and the lack
47 435 of correlation with the severity of pain and pathology. Nor does it show how the individual affects
48 436 pain presentation.
49
50 437

51 438 **Generalisability**

52 439 This epidemiological study that is generalisable to the UK population, demonstrates association but
53 440 not causality, and leaves unanswered questions as to what additional factors contribute to shoulder
54 441 pain. Particularly interesting is how individuals may or may not have painful shoulders irrespective of
55 442 the pathology. Further research into this could provide alternative targets to treatment methods, and
56 443 potentially reduce the cost of imaging modalities and surgical interventions.
57
58 444
59
60

445 Conclusion

446 In conclusion, this general population study has demonstrated that full-thickness rotator cuff tears are
 447 common affecting 22.1% of women over the age of 60, and tendon abnormalities affecting 59.4%.
 448 Despite 41.7% of individuals with a full-thickness tear (48.4% of all full-thickness tears) being
 449 asymptomatic, tendon abnormalities and tears are associated with pain. The likelihood, but not
 450 severity of symptoms, increases with greater structural damage.

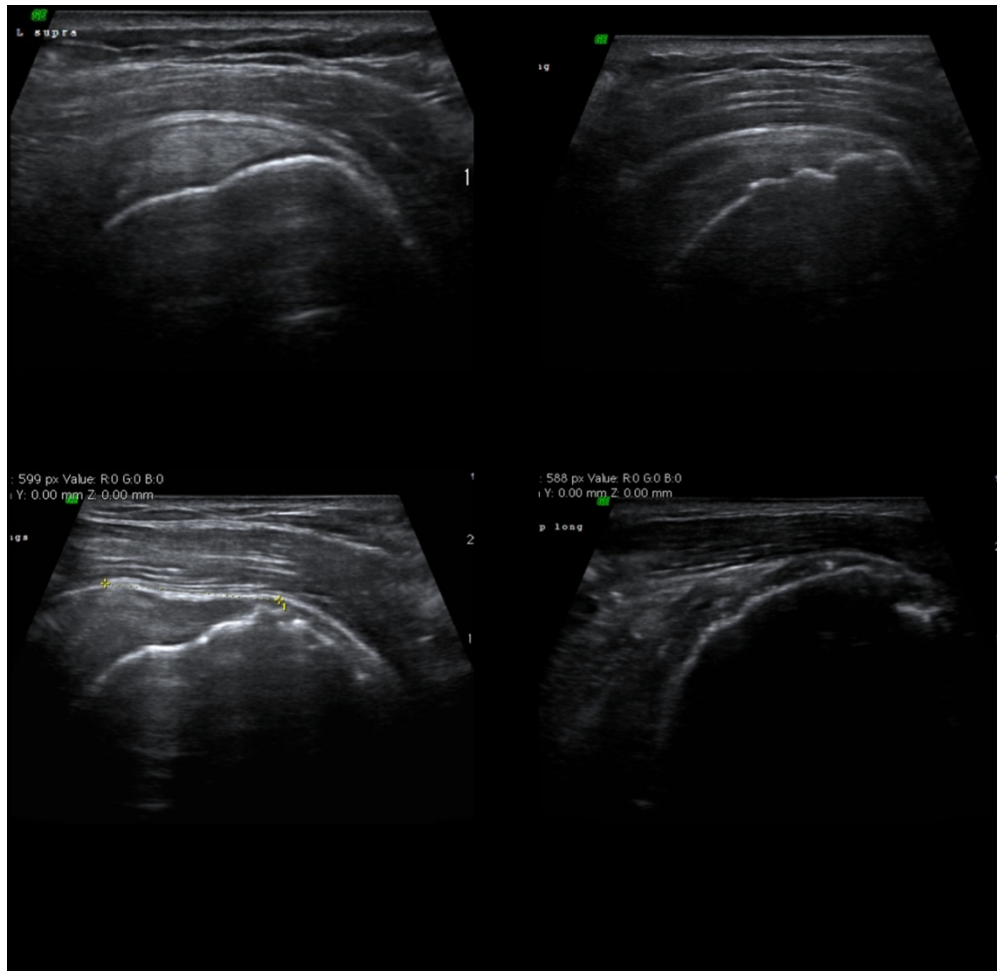
451
 452 This high prevalence and association of symptoms results in a significant impact on primary care
 453 health services, with 28.3% of this population having presented to a GP with shoulder pain. Of these a
 454 third had a full-thickness tear and a third had an abnormal but non-torn tendon. Overall, 8.9% of this
 455 cohort had seen their general practitioner with shoulder pain and a full-thickness tear, and 18.8% had
 456 seen their general practitioner with an abnormal or torn tendon.

457 REFERENCES

1. Vos T, Abajobir AA, Abate KH, et al. Global, regional, and national incidence, prevalence, and years lived with disability for 328 diseases and injuries for 195 countries, 1990-2016: a systematic analysis for the Global Burden of Disease Study 2016. *The Lancet* 2017;390(10100):1211-59. doi: 10.1016/S0140-6736(17)32154-2
2. Urwin M, Symmons D, Allison T, et al. Estimating the burden of musculoskeletal disorders in the community: the comparative prevalence of symptoms at different anatomical sites, and the relation to social deprivation. *Annals of the Rheumatic Diseases* 1998;57(11):649-55. doi: 10.1136/ard.57.11.649 [published Online First: 1999/01/30]
3. Pope DP, Croft PR, Pritchard CM, et al. Prevalence of shoulder pain in the community: the influence of case definition. *Annals of the Rheumatic Diseases* 1997;56(5):308-12. doi: 10.1136/ard.56.5.308
4. Bunker T. Rotator cuff disease. *Current Orthopaedics* 2002;16:223-33. doi: 10.1054/cuor.2002.0257
5. Meislin RJ, Sperling JW, Stitik TP. Persistent shoulder pain: epidemiology, pathophysiology, and diagnosis. *The American Journal of Orthopedics* 2005;34(12 Suppl):5-9. [published Online First: 2006/02/03]
6. Roquelaure Y, Ha C, Leclerc A, et al. Epidemiologic surveillance of upper-extremity musculoskeletal disorders in the working population. *Arthritis Rheumatology* 2006;55(5):765-78. doi: 10.1002/art.22222 [published Online First: 2006/10/03]
7. Ng Man Sun S, Gillott E, Bhamra J, et al. Implant use for primary hip and knee arthroplasty: are we getting it right first time? *The Journal of Arthroplasty* 2013;28(6):908-12. doi: 10.1016/j.arth.2012.11.012 [published Online First: 2013/03/20]
8. Hinsley H, Nicholls A, Daines M, et al. Classification of rotator cuff tendinopathy using high definition ultrasound. *Muscles Ligaments Tendons Journal* 2014;4(3):391-7. [published Online First: 2014/12/10]
9. Teefey SA, Rubin DA, Middleton WD, et al. Detection and quantification of rotator cuff tears. Comparison of ultrasonographic, magnetic resonance imaging, and arthroscopic findings in seventy-one consecutive cases. *The Journal of Bone and Joint Surgery American Volume* 2004;86(4):708-16. [published Online First: 2004/04/08]
10. de Jesus JO, Parker L, Frangos AJ, et al. Accuracy of MRI, MR arthrography, and ultrasound in the diagnosis of rotator cuff tears: a meta-analysis. *American Journal of Roentgenology* 2009;192(6):1701-7. doi: 10.2214/ajr.08.1241 [published Online First: 2009/05/22]
11. Naqvi GA, Jadaan M, Harrington P. Accuracy of ultrasonography and magnetic resonance imaging for detection of full thickness rotator cuff tears. *International journal of shoulder surgery* 2009;3(4):94-97. doi: 10.4103/0973-6042.63218
12. Smith TO, Back T, Toms AP, et al. Diagnostic accuracy of ultrasound for rotator cuff tears in adults: a systematic review and meta-analysis. *Clinical Radiology*

- 2011;66(11):1036-48. doi: 10.1016/j.crad.2011.05.007 [published Online First: 2011/07/09]
13. Dinnes J, Loveman E, McIntyre L, et al. The effectiveness of diagnostic tests for the assessment of shoulder pain due to soft tissue disorders: a systematic review. *Health Technology Assessment* 2003;7(29):iii, 1-166. doi: 10.3310/hta7290 [published Online First: 2003/10/22]
 14. Ottenheijm RP, Jansen MJ, Staal JB, et al. Accuracy of diagnostic ultrasound in patients with suspected subacromial disorders: a systematic review and meta-analysis. *Archives of Physical Medicine and Rehabilitation* 2010;91(10):1616-25. doi: 10.1016/j.apmr.2010.07.017 [published Online First: 2010/09/30]
 15. Fehring EV, Sun J, VanOeveren LS, et al. Full-thickness rotator cuff tear prevalence and correlation with function and co-morbidities in patients sixty-five years and older. *Journal of Shoulder and Elbow Surgery* 2008;17(6):881-5. doi: 10.1016/j.jse.2008.05.039 [published Online First: 2008/09/09]
 16. Milgrom C, Schaffler M, Gilbert S, et al. Rotator-cuff changes in asymptomatic adults. The effect of age, hand dominance and gender. *The Journal of Bone & Joint Surgery British Volume* 1995;77(2):296-8. [published Online First: 1995/03/01]
 17. Moosmayer S, Smith HJ, Tariq R, et al. Prevalence and characteristics of asymptomatic tears of the rotator cuff: an ultrasonographic and clinical study. *Journal of Bone and Joint Surgery British Volume* 2009;91(2):196-200. doi: 10.1302/0301-620x.91b2.21069 [published Online First: 2009/02/05]
 18. Tempelhof S, Rupp S, Seil R. Age-related prevalence of rotator cuff tears in asymptomatic shoulders. *Journal of Shoulder and Elbow Surgery* 1999;8(4):296-9. [published Online First: 1999/09/03]
 19. Reilly P, Macleod I, Macfarlane R, et al. Dead men and radiologists don't lie: a review of cadaveric and radiological studies of rotator cuff tear prevalence. *Annals of The Royal College of Surgeons of England* 2006;88(2):116-21. doi: 10.1308/003588406x94968 [published Online First: 2006/03/23]
 20. Yamamoto A, Takagishi K, Osawa T, et al. Prevalence and risk factors of a rotator cuff tear in the general population. *Journal of Shoulder and Elbow Surgery* 2010;19(1):116-20. doi: 10.1016/j.jse.2009.04.006 [published Online First: 2009/06/23]
 21. Schibany N, Zehetgruber H, Kainberger F, et al. Rotator cuff tears in asymptomatic individuals: a clinical and ultrasonographic screening study. *European Journal of Radiology* 2004;51(3):263-8. doi: 10.1016/s0720-048x(03)00159-1 [published Online First: 2004/08/06]
 22. Yamaguchi K, Ditsios K, Middleton WD, et al. The demographic and morphological features of rotator cuff disease. A comparison of asymptomatic and symptomatic shoulders. *Journal of Bone and Joint Surgery American Volume* 2006;88(8):1699-704. doi: 10.2106/jbjs.E.00835 [published Online First: 2006/08/03]
 23. Mall NA, Kim HM, Keener JD, et al. Symptomatic progression of asymptomatic rotator cuff tears: a prospective study of clinical and sonographic variables. *The Journal of Bone and Joint Surgery American Volume* 2010;92(16):2623-33. doi: 10.2106/jbjs.I.00506 [published Online First: 2010/11/19]
 24. Needell SD, Zlatkin MB, Sher JS, et al. MR imaging of the rotator cuff: peritendinous and bone abnormalities in an asymptomatic population. *American Journal of Roentgenology* 1996;166(4):863-7. doi: 10.2214/ajr.166.4.8610564 [published Online First: 1996/04/01]
 25. Sher JS, Uribe JW, Posada A, et al. Abnormal findings on magnetic resonance images of asymptomatic shoulders. *The Journal of Bone and Joint Surgery American Volume* 1995;77(1):10-5. doi: 10.2106/00004623-199501000-00002 [published Online First: 1995/01/01]
 26. Yamaguchi K, Tetro AM, Blam O, et al. Natural history of asymptomatic rotator cuff tears: a longitudinal analysis of asymptomatic tears detected sonographically. *Journal*

- 1
2
3 *of Shoulder and Elbow Surgery* 2001;10(3):199-203. doi: 10.1067/mse.2001.113086
4 [published Online First: 2001/06/16]
- 5 27. Chandnani V, Ho C, Gerharter J, et al. MR findings in asymptomatic shoulders: a blind
6 analysis using symptomatic shoulders as controls. *Clinical Imaging* 1992;16(1):25-
7 30. doi: 10.1016/0899-7071(92)90085-n [published Online First: 1992/01/01]
- 8 28. Minagawa H, Yamamoto N, Abe H, et al. Prevalence of symptomatic and asymptomatic
9 rotator cuff tears in the general population: From mass-screening in one village.
10 *Journal of orthopaedics* 2013;10(1):8-12. doi: 10.1016/j.jor.2013.01.008 [published
11 Online First: 2014/01/10]
- 12 29. Harris JD, Pedroza A, Jones GL. Predictors of pain and function in patients with
13 symptomatic, atraumatic full-thickness rotator cuff tears: a time-zero analysis of a
14 prospective patient cohort enrolled in a structured physical therapy program.
15 *American Journal of Sports Medicine* 2012;40(2):359-66. doi:
16 10.1177/0363546511426003 [published Online First: 2011/11/19]
- 17 30. Yamamoto A, Takagishi K, Kobayashi T, et al. Factors involved in the presence of
18 symptoms associated with rotator cuff tears: a comparison of asymptomatic and
19 symptomatic rotator cuff tears in the general population. *Journal of Shoulder and*
20 *Elbow Surgery* 2011;20(7):1133-7. doi: 10.1016/j.jse.2011.01.011 [published Online
21 First: 2011/04/02]
- 22 31. Arden NK, Griffiths GO, Hart DJ, et al. The association between osteoarthritis and
23 osteoporotic fracture: the Chingford Study. *The British Journal of Rheumatology*
24 1996;35(12):1299-304. doi: 10.1093/rheumatology/35.12.1299 [published Online
25 First: 1996/12/01]
- 26 32. Hart DJ, Mootoosamy I, Doyle DV, et al. The relationship between osteoarthritis and
27 osteoporosis in the general population: the Chingford Study. *Annals of the Rheumatic*
28 *Diseases* 1994;53(3):158-62. doi: 10.1136/ard.53.3.158 [published Online First:
29 1994/03/01]
- 30 33. Hart DJ, Spector TD. The relationship of obesity, fat distribution and osteoarthritis in
31 women in the general population: the Chingford Study. *Journal of Rheumatology*
32 1993;20(2):331-5. [published Online First: 1993/02/01]
- 33 34. Dawson J, Fitzpatrick R, Carr A. Questionnaire on the perceptions of patients about
34 shoulder surgery. *The Journal of Bone and Joint Surgery British Volume*
35 1996;78(4):593-600. [published Online First: 1996/07/01]
- 36 35. Dawson J, Rogers K, Fitzpatrick R, et al. The Oxford shoulder score revisited. *Archives of*
37 *Orthopaedic and Trauma Surgery* 2009;129(1):119-23. doi: 10.1007/s00402-007-
38 0549-7 [published Online First: 2008/01/10]
- 39 36. Murphy RJ, Daines MT, Carr AJ, et al. An independent learning method for orthopaedic
40 surgeons performing shoulder ultrasound to identify full-thickness tears of the rotator
41 cuff. *The Journal of Bone and Joint Surgery American Volume* 2013;95(3):266-72.
42 doi: 10.2106/jbjs.K.00706 [published Online First: 2013/02/08]
- 43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60



Tendon classification on ultrasound: (i) normal tendon: normal homogenous appearance throughout with no abnormality at the enthesis; (ii) abnormal tendon: loss of homogenous appearance and abnormal ragged enthesis +/- enlarged fluid-filled bursa or partial thickness tear; (iii) full thickness tear (0-2.5cm): lucent patch through the full thickness of the tendon with tear size defined as its width in the sagittal plane (iv) full-thickness tears (>2.5cm): Evidence of large defect or no evidence of tendon tissue present.

106x102mm (300 x 300 DPI)

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

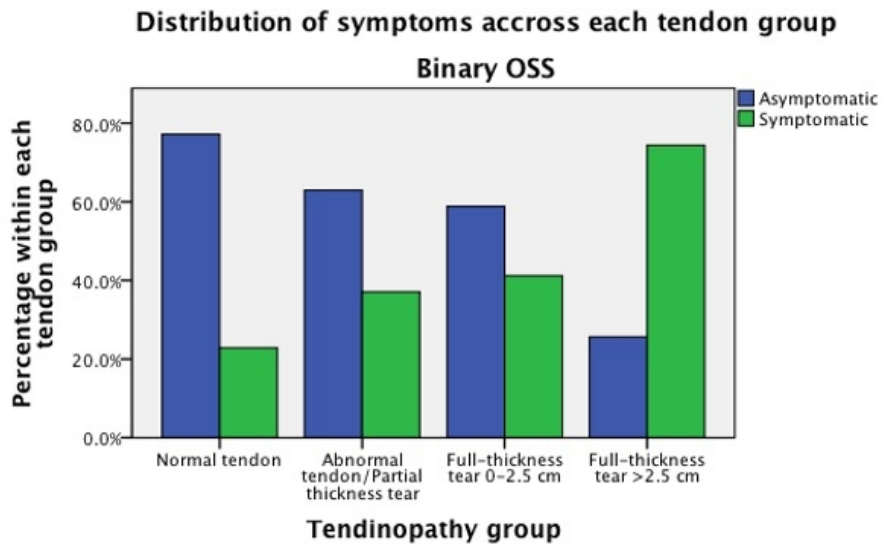


Figure 2. Distribution of symptoms across each tendon group

116x68mm (144 x 144 DPI)

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No.	Recommendation	Page No.	Relevant text from manuscript
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	Page 1 -	title of the manuscript
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	Page 3	
Introduction				
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Page 4 -	line 128-153
Objectives	3	State specific objectives, including any prespecified hypotheses	page 4	lines 150-154
Methods				
Study design	4	Present key elements of study design early in the paper	Page 4 -	lines 165-176
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Page 4 -	lines 165-176
Participants	6	(a) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up <i>Case-control study</i> —Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls <i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants (b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed <i>Case-control study</i> —For matched studies, give matching criteria and the number of controls per case	Pages -	lines 165-176
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Page 5 -	lines 182-198
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Page 5 -	lines 181-198
Bias	9	Describe any efforts to address potential sources of bias	Page 10 -	lines 351-393
Study size	10	Explain how the study size was arrived at	Page 4 -	Lines 174-177

Continued on next page

Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Page 5-6 - lines 207-236
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding (b) Describe any methods used to examine subgroups and interactions (c) Explain how missing data were addressed (d) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed <i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed <i>Cross-sectional study</i> —If applicable, describe analytical methods taking account of sampling strategy (e) Describe any sensitivity analyses	SECTION 12 - Page 5-6 - lines 207-236
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed (b) Give reasons for non-participation at each stage (c) Consider use of a flow diagram	Page 6 - lines 239-246
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders (b) Indicate number of participants with missing data for each variable of interest (c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)	Page 6 - lines 239-246
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time <i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure <i>Cross-sectional study</i> —Report numbers of outcome events or summary measures	Pages 6-9
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included (b) Report category boundaries when continuous variables were categorized (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	Results tables, pages 6-9 - lines 248-325

Continued on next page

Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Not applicable
Discussion			
Key results	18	Summarise key results with reference to study objectives	Page 9- lines 328-351
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	Page 10 - 356-392
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Page 11 - lines 422-437
Generalisability	21	Discuss the generalisability (external validity) of the study results	Page 11 - lines 440-445
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Page 2 - lines 50-53

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

Prevalence of rotator cuff tendon tears and symptoms in a Chingford general population cohort, and the resultant impact on United Kingdom health services: A cross-sectional observational study.

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2021-059175.R2
Article Type:	Original research
Date Submitted by the Author:	18-May-2022
Complete List of Authors:	Hinsley, Hannah; University of Oxford Nuffield Department of Orthopaedics Rheumatology and Musculoskeletal Sciences Ganderton, Charlotte; Swinburne University of Technology Faculty of Health Arts and Design, Nursing and Allied Health Arden, Nigel; University of Oxford , University of Oxford Nuffield Department of Orthopaedics Rheumatology and Musculoskeletal Sciences, Carr, Andrew; University of Oxford, University of Oxford Nuffield Department of Orthopaedics Rheumatology and Musculoskeletal Sciences,
Primary Subject Heading:	Public health
Secondary Subject Heading:	Diagnostics, Evidence based practice, Sports and exercise medicine
Keywords:	Shoulder < ORTHOPAEDIC & TRAUMA SURGERY, Ultrasonography < OBSTETRICS, Musculoskeletal disorders < ORTHOPAEDIC & TRAUMA SURGERY, Diagnostic radiology < RADIOLOGY & IMAGING

SCHOLARONE™
Manuscripts



I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our [licence](#).

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which [Creative Commons](#) licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

1
2
3 1 **Prevalence of rotator cuff tendon tears and symptoms in a Chingford general population**
4 2 **cohort, and the resultant impact on United Kingdom health services: A cross-sectional**
5 3 **observational study.**
6 4

7 5 Hannah Hinsley^{1*}, Charlotte Ganderton², Nigel Arden^{1^}, Andrew Carr^{1^}

8 6 ¹ The Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, University
9 7 of Oxford, Oxford, United Kingdom

10 8 ² Department of Health Sciences and Biostatistics, Faculty of Health Arts and Design, Swinburne
11 9 University of Technology, Hawthorn, Victoria, Australia

12
13
14
15
16 10
17 11 **Author information:**

18 12 Dr Hannah Hinsley; Orthopaedic Surgeon, ARUK orthopaedic clinical research fellow, The Nuffield
19 13 Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, University of Oxford,
20 14 United Kingdom; hannahoag@doctors.org.uk

21 15
22 16 [^]Professor Nigel Arden; Lead of Musculoskeletal Epidemiology, Deputy Director Centre for Sport,
23 17 Exercise & Osteoarthritis Research Versus Arthritis and Fellow at the Lady Margaret Hall at The
24 18 Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, University of
25 19 Oxford, United Kingdom; nigel.arden@ndorms.ox.ac.uk

26 20
27 21 Dr Charlotte Ganderton, Physiotherapist and Lecturer at the Department of Health Sciences and
28 22 Biostatistics, Faculty of Health Arts and Design, Swinburne University of Technology, Hawthorn,
29 23 Victoria, Australia, cganderton@swin.edu.au

30 24
31 25 [^]Professor Andrew Carr, Professor of Orthopaedics at The Nuffield Department of Orthopaedics,
32 26 Rheumatology and Musculoskeletal Sciences, University of Oxford, United Kingdom; Director of the
33 27 Botnar Research Centre; andrew.carr@ndorms.ox.ac.uk

34 28
35 29 *Corresponding author: Dr Hannah Hinsley

36 30 Contact address: Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences,
37 31 NIHR Biomedical Research Unit, Botnar Research Centre, University of Oxford, Nuffield
38 32 Orthopaedic Centre, Windmill Road, OX3-7LD Oxford, United Kingdom
39 33 Email: hannahoag@doctors.org.uk

40 34
41 35 [^]Senior co-authors
42 36
43 37
44 38
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

1
2
3 39 **Contributors:** HH, NA, AC were responsible for planning, conducting, and reporting the work
4 40 described in the article. HH and CG drafted the manuscript. All authors approved the final version of
5 41 the article. HH, NA and AC had access to all the data in the study and can take responsibility for the
6 42 integrity of the data and the accuracy of the data analysis. HH is guarantor. The corresponding author
7 43 attests that all listed authors meet authorship criteria and that no others meeting the criteria have been
8 44 omitted. All authors fully acknowledge the contribution of the patients that participated in this study.
9 45 No authors are employees of the National Institutes of Health.

10
11
12
13 46 **Transparency Statement:** The lead author (the manuscript's guarantor) affirms that the manuscript
14 47 is an honest, accurate, and transparent account of the study being reported; that no important aspects
15 48 of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant,
16 49 registered) have been explained.

17 50
18 51 **Role of the funding source:** Arthritis Research United Kingdom awarded the project £190,361.00 to
19 52 cover costs to completion. Researchers were independent from the funding body. All authors, external
20 53 and internal, had full access to all the data (including statistical reports and tables) in the study and
21 54 can take responsibility for the integrity of the data and the accuracy of the data analysis.

22 55
23 56 **Competing interests:** No competing interests

24 57
25 58 **Ethics approval:** Outer North East London Research Ethics Committee (formerly Barking and
26 59 Havering and Waltham Forest RECs), LREC (R&WF) reference ID = 96.

30 60 **Acknowledgement**

31 61 Thank you to Dr Gemma Wallis, Statistician, for reviewing statistical analysis processes used in this
32 62 study.
33 63

34 64
35 65 **Data sharing:** For information about the Chingford 1000 Women Study,
36 66 email chingford@ndorms.ox.ac.uk.

37 67
38 68 **Dissemination to participants and related patient and public communities:** We will disseminate
39 69 our findings to patient organisations and media outlets.

40 70
41 71 **Provenance and peer review:** Not commissioned; peer reviewed at Orthopaedic meetings.
42 72
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Structured Abstract

Objectives:

To define the population prevalence of rotator cuff tears and test their association with pain and function loss; determine if severity symptom correlates with tear stage severity, and quantify the impact of symptomatic rotator cuff tears on primary health care services, in a general population cohort of women.

Design:

Cross sectional observational study.

Participants:

Individuals were part of the Chingford 1000 women cohort, a 20-year-old longitudinal population study comprising 1003 women aged between 64 and 87, and representative of the population of the UK.

Main outcome measures:

Rotator cuff pathology prevalence on ultrasound, shoulder symptoms using the Oxford shoulder score, and resultant number of GP consultations.

Results:

The population prevalence of full-thickness tears was 22.2%, which increased with age ($p=0.004$), and whether it was the dominant arm (RR 1.64, OR 1.58, 95% CI 1.07-2.33, $p=0.021$).

Although 48.4% of full-thickness tears were asymptomatic there was an association between rotator cuff tears and patient reported symptoms. Individuals with at least one full-thickness tear were 1.97 times more likely, than those with bilateral normal tendons (OR 3.53, 95%CI 2.00-5.61, $p<0.001$), to have symptoms. Severity of symptoms was not related to the severity of the pathology until tears are $>2.5\text{cm}$ ($p=0.009$).

In the cohort 8.9% had seen their GP with shoulder pain and a full-thickness rotator cuff tear, 18.8% with shoulder pain and an abnormality and 29.3% with shoulder pain.

Conclusion:

Rotator cuff tears are common, and primary care services are heavily impacted. As 50% of tears remain asymptomatic, future research may investigate the cause of pain and whether different treatment modalities, aside from addressing the pathology, need further investigation.

Trial Registration:

The local ethics committee approved the study (Outer North East London Research Ethics Committee (formerly Barking and Havering and Waltham Forest RECs), LREC (R&WF) reference ID = 96).

Strengths and limitations of this study:

- Pain on the Oxford Shoulder Score is associated with the presence of rotator cuff tendon pain, but not the extent of structural pathology identified on ultrasound imaging.
- Rotator cuff pathology and associated symptoms pose a large burden on the healthcare system with 28.8% of people seeking GP consultation for their shoulder pain.
- This epidemiological study demonstrates association but not causality and leaves unanswered questions as to what additional factors contribute to shoulder pain.

122 Introduction

123 Background

124 Musculoskeletal pain is one of the most common sources of disability in the Western world¹. The
125 shoulder is the third most common site of musculoskeletal disease², with an estimated 20% of the
126 population reporting pain at any given time³. Pain related to rotator cuff tears are estimated to account
127 for 30-40% of these shoulder complaints⁴, causing high levels of disability and associated healthcare
128 costs⁵⁻⁷. High-definition ultrasound is the current gold standard for the detection of full-thickness
129 tears, and is a valid tool to detect an abnormal tendon enthesis⁸, but has poorer accuracy to detect
130 partial-thickness tears⁸⁻¹⁴. Full thickness tears are recognised to be common and associated with
131 increasing age¹⁵⁻¹⁸, however prevalence in symptomatic and asymptomatic shoulders varies widely
132 across cadaveric¹⁹, radiological¹⁹ and retrospective cohort studies^{16-18 20-28}. Furthermore, the presence
133 of selection bias in studies undertaken in rotator cuff tendon tears¹⁶⁻²⁸, has meant population-based
134 studies available, are not representative of Western demographics. Thus, research in this area may
135 lead to a better understanding of the natural history of rotator cuff tears.

136
137 Clinical manifestations of rotator cuff tears are varied^{15 17 22 26 28}, and detection of pathology and its
138 relationship to clinical symptoms is not well established. Many tears are asymptomatic but are
139 thought to be a risk of developing symptoms with time²⁶. Although larger tears are more likely to be
140 painful, there is also no evidence to suggest that they have a greater severity of symptoms than
141 smaller tears²⁹. One population cohort from a mountainous region has suggested that only a third of
142 full-thickness tears were painful, of which symptoms were more prevalent in the dominant arm³⁰.
143 However, all studies investigating symptom association have looked at isolated shoulders, and have
144 not considered that the individual, has two shoulders. It is therefore plausible that there may be the
145 presence of other physical or psychological factors unique to the individual, rather than the specific
146 shoulder, that may have an influence on symptom presentation, rather than solely the underlying
147 pathology. To date, no study has explored the association between rotator cuff tears, pain and
148 functional loss in a general population cohort, or how these impact on a health service.

150 Objectives

151 This study aims to: (i) describe the population prevalence of different stages of rotator cuff tear in a
152 general population cohort of women; (ii) determine what proportion of rotator cuff tears are
153 symptomatic, and whether the severity of symptoms correlates with tear stage severity; (iii) identify
154 individual influences on the likelihood of symptoms and (iv) quantify the impact of symptomatic
155 rotator cuff tears on primary health care services.

157 Methods

158 *Study Design, Setting and Participants (including study size)*

159 Participants in this cross-sectional observational study were involved in the larger Chingford 1000
160 women study. This is an ethically approved well described prospective population-based longitudinal
161 study of osteoarthritis and osteoporosis comprising 1003 white Caucasian women, derived from the
162 register of a large general practice in Chingford, North London³¹⁻³³. The cohort was recruited in 1989
163 where the women were aged 44-67. They have been characterised as representative of women in the
164 UK general population with respect to weight, height, and smoking characteristics. The cohort has
165 been subsequently listed by the National Institute for Health Research as an important
166 epidemiological resource. This study took place at the Chingford 20 year follow up visit where 516 of
167 the original 1003 cohort attended (158 women had died, 111 were unable to attend, 218 had moved
168 away or been lost to follow up). A musculoskeletal assessment, including the Oxford shoulder score,

1
2
3 169 and shoulder ultrasound examination was performed on both shoulders (left and right) in 463 women
4 170 (Out of the 515, 52 attended but did not have a shoulder assessment due to lack of assessor, and 1 did
5 171 not complete an Oxford shoulder score). The local ethics committee approved the study and consent
6 172 was obtained from each woman (Outer North East London Research Ethics Committee (formerly
7 173 Barking and Havering and Waltham Forest RECs), LREC (R&WF) reference ID = 96).

8 174

9 175 *Variables and data sources:*

10 176 Participant characteristics of age, height, weight, hand dominance, and a self-reported
11 177 musculoskeletal questionnaire filled out a priori (including the Oxford Shoulder Score^{34 35}, body chart
12 178 and questions regarding previous pain, treatments and whether medical advice has been sought), were
13 179 all collected at baseline. A musculoskeletal ultrasound assessment on bilateral shoulders was then
14 180 undertaken using a fixed SOPP (standard operating procedure protocol).

15 181

16 182 The ultrasound examination of the 464 women was completed by two orthopaedic assessors and
17 183 performed using a GE voluson i-portable ultrasound machine with a 10-16MHz linear probe.
18 184 Ultrasound training and appropriate validation studies³⁶ were completed as recommended by the
19 185 BESS focus group - 343 individuals were scanned by assessor 1 and 121 individuals by assessor two.
20 186 Appropriate inter and intra-rater reliability studies were performed and showed high reproducibility
21 187 (weighted kappa 0.92 $p < 0.001$) and no difference in reporting trends ($p = 0.08$). The ultrasound
22 188 protocol was derived according to the recommendations of the Nuffield Orthopaedic Centre
23 189 Musculoskeletal radiology department. Tendons were classified into one of four working groups
24 190 based upon ultrasound measurements as validated by Hinsley et al.⁸: normal tendon; abnormal tendon
25 191 and partial thickness tear; single tendon full-thickness tears (0-2.5cm) and multi-tendon full-thickness
26 192 tears (> 2.5 cm) (Figure 1).

27 193

28 194 [INSERT FIGURE 1]

29 195

30 196 *Quantitative variables and Statistical methods*

31 197 All statistics were performed using IBM SPSS Statistics version 22 (IBM, Armonk, NY, USA).
32 198 Age, BMI, hand dominance, and symptom presence were compared across the four different tendon
33 199 pathology groups. Wilcoxon rank sum test, one-way ANOVA, and chi-squared tests were used for
34 200 non-normal, normal and categorical data respectively.

35 201

36 202 Population prevalence of full-thickness tears was defined as having at least one unilateral full-
37 203 thickness tear. Population prevalence of tendon abnormalities was defined as having at least a
38 204 unilateral tendon abnormality ranging from abnormal enthesis to a full thickness tear. This was
39 205 calculated by summing the percentage with unilateral tears and the percentage with bilateral tears for
40 206 each age group.

41 207

42 208 Symptoms were defined using the Oxford shoulder score^{34 35}. This was chosen for what the authors
43 209 believed represented the best content and construct validity as applicable to the study as it covers a
44 210 range of symptoms (both relating to pain and function) over a 4-week time period, and also allows
45 211 discriminate ability. Binary symptoms were defined by dichotomising the Oxford shoulder score^{34 35}
46 212 where, any non-perfect score ($\leq 47/48$) was classified as symptomatic. The cut off at 47 was used to
47 213 determine symptoms as we were not looking for significant changes, rather, the ability to detect any
48 214 individual who was unable to perform an activity to the full, or who has pain at any given time. We
49 215 validated this by running a Pearson correlation sub analysis between the OSS pain subset with the
50 NRS ($R = 0.816$, $p < 0.001$, 95% CI 0.793-0.836) and a simple binary question ($R = 0.812$, $p < 0.001$, 95%

216 CI 0.789-0.833), and the full OSS with a binary pain question ($R=0.759$, $p<0.001$, 95% CI 0.730-
 217 0.785). Furthermore, we re-ran the analysis using a 3-point difference to reflect a clinically significant
 218 difference between groups and the results were not significantly different. Where questions are pain
 219 specific, the four pain specific questions of the OSS were used as a sub-scale. In symptomatic
 220 participants, the full OSS scale, scored on a 0-48 point scale, was used to define symptom severity. A
 221 χ^2 test was used to determine any difference between tendon pathology groups. Multivariate binary
 222 logistic regression was used to adjust for the potential confounders age, BMI and hand dominance
 223 determined a priori. To account for a high positive skew of the OSS data when determining symptom
 224 severity, all asymptomatic shoulders were removed, and a logarithmic transformation of the inverse
 225 OSS was used to create a normal distribution. Symptom severity in symptomatic shoulders was
 226 compared across tendon pathology groups using a 1-way ANOVA. Multivariate linear regression was
 227 used to adjust for potential confounders age, and hand dominance determined a priori.

229 Patient and public involvement

230 We would like to thank all the participants of the Chingford Women Study for their time.
 231 We would also like to thank Mrs Maxine Daniels and Dr Alan Hakim for their time and dedication,
 232 and both Mr Alex Nichols and Mr Michael Daines for their assistance with data collection and Dr
 233 Gemma Wallis for her assistance with data analysis.

234 Results

235 Participants and descriptive data

236 464 individuals (928 shoulders) were included in the study (Table 1). The distribution of age across
 237 each tendon pathology group was significantly different ($p<0.001$), with age increasing in accordance
 238 with tear severity. There was a statistical difference in the proportion of dominant and non-dominant
 239 arms in each tendon pathology group ($p=0.033$), with there being significantly more non-dominant
 240 arms in the normal tendon group ($p=0.010$), and significantly more dominant arms in those with full-
 241 thickness tears ($p=0.026$). There were no between-group differences in BMI ($p=0.080$).

243 Table 1. Demographics of all the shoulders included in the study

	Frequency	%	Median age	Mean BMI	Dominant arm (%)
Normal	510	55.0%	70	27.5	46.1%
Abnormal/ Partial tear	294	31.7%	73	28.0	52.7%
Full-thickness tears (0-2.5cm)	85	9.2%	74	27.9	58.8%
Full-thickness tears (>2.5cm)	39	4.2%	74	29.6	61.5%
All	928	100%	71	27.8	50%

244 Outcome data and main results

245 *Prevalence of rotator cuff tendon pathology*

246 The population prevalence of having at least one full-thickness tear was 22.2% (4.5% bilateral). For
 247 age groups 60-69, 70-79 and 80-89 these were 14.9%; 25.9% and 29% respectively, and bilateral tears
 248 2.3%; 5.9% and 5.8% respectively. The difference in prevalence between age groups was statistically
 249 different ($p<0.001$).

250
 251 The population prevalence of having at least a unilateral tendon pathology or tear was 59.5% (30.6%
 252 bilateral). For age groups 60-69, 70-79 and 80-89 these were 51.5%; 61.8% and 72.5% respectively,

and bilateral tears 24.6%; 32.3% and 40.6% respectively. The difference in population prevalence between age groups was statistically significant ($p<0.001$).

Table 2 shows the prevalence of rotator cuff tendinopathy in the dominant and non-dominant arms in age deciles. The distribution of tendinopathy differed between age groups (Dominant arm $p=0.002$; non-dominant arm $p=0.037$) with more pathology found in older age groups, and in the dominant compared to non-dominant arms ($p=0.004$). There was no difference in prevalence according to BMI group. The relative risk of full-thickness tear was 1.64 (OR 1.580, 95%CI 1.073-2.326, $p=0.021$) in the dominant compared to non-dominant arm. For those aged 70-79 it was 2.072 (OR 2.026, 95%CI 1.286-3.190, $p=0.002$), and aged 80-89 was 2.293 (OR 2.256, 95%CI 1.264-4.027, $p=0.006$), compared to those aged 60-69.

Table 2. Prevalence of rotator cuff tendon pathology according to age decile and arm dominance

	Age Group							
	60-69 (n=175)		70-79 (n=220)		80-89 (n=69)		Total (n=464)	
	Count	%	Count	%	Count	%	Count	%
Dominant arm								
Normal tendon	102	58.3%	111	50.5%	22	31.9%	235	50.6%
Abnormal tendon/Partial thickness tear	54	30.9%	67	30.5%	34	49.3%	155	33.4%
Full-thickness tear 0-2.5 cm	14	8.0%	27	12.3%	9	13.0%	50	10.8%
Full-thickness tear >2.5 cm	5	2.9%	15	6.8%	4	5.8%	24	5.2%
Non-dominant arm								
Normal tendon	115	65.7%	122	55.5%	38	55.1%	275	59.3%
Abnormal tendon/Partial thickness tear	49	28.0%	70	31.8%	20	29.0%	139	30.0%
Full-thickness tear 0-2.5 cm	10	5.7%	18	8.2%	7	10.1%	35	7.5%
Full-thickness tear >2.5 cm	1	0.6%	10	4.5%	4	5.8%	15	3.2%

266

267 Association of symptoms (all shoulders)

268 An analysis of symptom association was completed in 926 shoulders (463/464 participants due to loss
 269 of one questionnaire). There were 289 (31.2%) symptomatic shoulders according to a dichotomised
 270 OSS. The presence of symptoms was statistically significant between tendon groups ($p<0.001$);
 271 51.6% of all full-thickness tears were symptomatic. There was no difference in age, BMI or arm
 272 dominance between symptomatic or asymptomatic shoulders. The relative risks of having symptoms
 273 compared to those with a reported normal tendon were as follows: Abnormal/Partial tears 1.969 (OR
 274 1.991, 95%CI 1.454-2.727); full-thickness tears 0-2.5cm 2.203 (OR 2.366, 95%CI 1.465-3.891); and
 275 full-thickness tears >2.5cm 4.718 (OR 9.800, 95%CI 4.638-20.705). All were significant ($p<0.001$)
 276 with the model correctly predicting 71% of symptom outcomes correctly. The distribution of
 277 symptoms across each tendon group is shown in Figure 2.

278

279 When the same analysis was performed using a 3-point change in the OSS to define symptoms the
 280 results were not statistically different and compared to normal tendons were as follows:

281 Abnormal/Partial tears 1.793 (OR 1.936, 95%CI 1.374-2.726); full-thickness tears 0-2.5cm 2.098 (OR
 282 2.506, 95%CI 1.513-4.150); and full-thickness tears >2.5cm 3.924 (OR 9.678, 95%CI 4.784-19.580).
 283 All were significant ($p<0.001$).

283

284 [INSERT FIGURE 2]

285 *Symptom severity*

286 For the 289 symptomatic shoulders the full OSS was reported (Table 3). Median age was significantly
 287 different between groups ($p=0.047$), with age increasing with tear stage severity. No statistically
 288 significant between-group differences in BMI were identified, nor any within-group differences for
 289 arm dominance.

290
 291 Table 3. Demographics of the 289 symptomatic shoulders

	N	Median age	Mean BMI	Dominant arm (%)
Normal	116	70	28.3	46.6%
Abnormal/Partial tear	109	73	28.4	54.1%
Full-thickness tears 0-2.5cm	35	72	28.1	62.9%
Full-thickness tears >2.5cm	29	73	30.3	58.6%
All	289	71	28.5	50%

292
 293 The mean OSS for symptomatic shoulders was 41.8. For normal tendons this was 42.5, abnormal
 294 tendons, 42.1; full-thickness tears (0-2.5cm), 40.2; and full-thickness tears (>2.5cm), 38.4. There was
 295 a statistical difference between the groups (1 way ANOVA $p=0.030$). Linear regression analysis after
 296 adjustment for age, BMI, and hand dominance (no interactions identified), showed that the only
 297 significant difference in OSS scores was between normal tendons (mean OSS 42.5) and large full-
 298 thickness tears (OSS 38.3), $p=0.009$, power 0.75 (overall model $p=0.007$, power 0.892).

300 *Association of symptoms (individuals)*

301 Table 4 shows the relationship between the individual, presence of full-thickness rotator cuff tear and
 302 the likelihood of symptoms. A clustering effect of bilateral symptoms or lack thereof is present,
 303 irrespective of the underlying pathology. After adjustment for age and BMI, compared to those with
 304 bilaterally normal shoulders the relative risk of having at least one symptomatic shoulder in the
 305 presence of a full thickness rotator cuff tear is 1.49 (OR 1.867, 95%CI 1.200-2.904), and 1.97 (OR
 306 3.352, 95%CI 2.003-5.609) in the presence of at least a unilateral abnormality or cuff tear.

307
 308 Table 4. Distribution of individual shoulder symptoms according to the presence of full-thickness
 309 tears or tendon abnormalities

	No Symptoms	Unilateral Symptoms	Bilateral Symptoms	Total
Bilateral No FTT	226	71	63	360
Unilateral FTT	33	25	24	82
Bilateral FTT	10	3	8	21
Bilateral normal	131	28	28	187
Unilateral abnormality	72	34	28	134
Bilateral abnormality	66	37	39	142
Total	269	99	95	463

310 *Shoulder pain and use of primary care health services*

311 Table 5 shows the proportion of individuals with shoulder pain, past or present, seeking medical
 312 advice. The likelihood of seeking medical attention for shoulder pain was statistically different
 313 between each pathology group (Chi² test p=0.005) reflecting the increasing likelihood of pain.
 314 However, of those with pain the likelihood of seeking medical attention was not statistically different
 315 between groups (Chi² test p=0.179). Overall, 28.3% (131/463) of all individuals had at some stage
 316 seen their GP for shoulder pain. In this cohort, 8.9% (41/463) had seen their GP with shoulder pain
 317 and a full-thickness tendon tear and 18.8% (87/463) had seen their GP with an abnormal tendon or
 318 full thickness tear.

319
 320 A multivariable regression model using all individuals was used to predict the likelihood of attending
 321 a GP for shoulder pain. The presence of at least one full-thickness tear had a relative risk of 1.63 (OR
 322 2.179, 95%CI 1.282-3.703) compared to those with normal tendons of attending the GP. There was
 323 no statistical difference in relative risk of those with any tendon abnormality compared to those with
 324 bilaterally normal shoulders.

325

326 Table 5. Proportion of individuals seeking medical advice

	Present symptoms (either shoulder)		Past or Present symptoms (either shoulder)		All individuals % seen GP
	%	% seen GP	%	% seen GP	
All individuals (n=463)	41.9 (n=194)	44.8 (n=87)	55.7 (n=258)	50.8 (n=131)	28.3 (n=131)
Bilaterally normal tendons (n=187)	29.9 (n=56)	41.1 (n=23)	48.1 (n=90)	48.9 (n=44)	23.5 (n=44)
At least one abnormality (no tear) (n=173)	45.1 (n=78)	41.0 (n=32)	57.2 (n=99)	46.5 (n=46)	26.6 (n=46)
At least one full- thickness tear (n=103)	58.3 (n=60)	53.3 (n=32)	67.0 (n=69)	59.4 (n=41)	39.8 (n=41)

327

328 **Discussion**

329 **Key results**

330 Using a large general population cohort of women aged 65-84 years, this study has reported on the
 331 prevalence of rotator cuff pathology, the association of pathology to symptoms and uniquely the
 332 consequential impact on health services.

333

334 The prevalence of rotator cuff pathology has been well reported in the literature, and this general
 335 population study, supports previous findings. Prevalence was found to increase with every decile of
 336 age, and the relative risk of having a full thickness tear increased more than two-fold between the 65-
 337 69 and >80 age groups, suggesting age related change¹⁸. Overall, the prevalence of at least a unilateral
 338 full thickness tear was 22%. The dominant arm was 1.64 times likely to be affected, inferring that the
 339 presence of pathology may exist in shoulders with higher cumulative loading.

340
341 The relative risk of having symptomatic pathology (worsening OSS scores) increased with tear stage
342 severity, though the severity of symptoms did not increase accordingly. Although larger tear size
343 increased the likelihood of symptom presence, 48.4% of full-thickness rotator cuff tears remained
344 asymptomatic.

345
346 The burden of musculoskeletal shoulder pain on health services is large, with 28.3% of individuals in
347 this general population cohort having at some point sought medical advice for shoulder symptoms.
348 This is the first study to look at the impact of rotator cuff pathology on the impact on the health
349 services. Although on average only 50% of individuals with symptomatic rotator cuff tendon
350 pathology (tendinopathy) will seek medical advice, the impact remains significant. Overall, almost
351 10% of individuals in the general population have sought medical advice for shoulder symptoms in
352 the presence of a full-thickness tear, and almost 20% of the population for any tendon abnormality.
353 The major strength of this study is that it uses a large population-based cohort, and therefore not
354 subject to selection bias. The cohort was originally investigated with the primary focus of
355 osteoporosis, and not shoulder symptoms, thus any continued participation is not driven by shoulder
356 symptoms.

357 358 **Limitations (including bias)**

359 The cohort can only comment on associations in women aged between 65 and 84, but as previous
360 studies have found no relationship between symptoms and age or sex^{23 30}, this will not bias the
361 results. Potential survival bias is introduced by the cohort being in its 20th year. If a greater proportion
362 of individuals with pathology were lost to follow up this may cause us to under-estimate any
363 association, however, no known associations exist in the literature between rotator cuff tears and other
364 medical co-morbidities. Furthermore, as the prime goal of the cohort was not to investigate shoulder
365 symptoms, this had no impact on continued study participation. Furthermore, only 463/516
366 individuals that attended the year-20 study underwent a shoulder examination due to lack of an
367 examiner being present at these follow up appointments. However, the age and BMI of the groups
368 was not statistically different to the full cohort.

369
370 Bias arising from having two examiners was ameliorated by two inter-observer reproducibility studies
371 that demonstrated minimal effect of inter-observer analytic bias. Furthermore, to demonstrate
372 ultrasound-scanning accuracy a learning curve study was undertaken a priori by both examiners,
373 which demonstrated scanning accuracies comparable to those quoted in the literature. Inter-observer
374 studies also demonstrated good reproducibility reducing analytic bias. Potential risk of overreporting
375 pathology in symptomatic presentations is acknowledged as the assessor (ultrasonographer) was
376 unblinded to the OSS result, as for pragmatic reasons due to lack of assessors, both assessments were
377 carried out by the same individual. To overcome this, a small intra-observer study was completed,
378 and an additional ultrasound scan was performed on 18 willing participants. The examiner was blind
379 to all previous results and shoulder scores. Overall agreement gave a weighted kappa score of 0.915
380 ($p < 0.001$).

381
382 The effect of tear size on symptom severity may have been underestimated in this study. The inability
383 to transform the complete data set due to the skew of the OSS data, meant all asymptomatic shoulders
384 had to be removed. Pain severity in the presence of a tear was then compared to a pain severity in a
385 normal (no tendon pathology) shoulder. We recognise that there may be many causes of shoulder pain
386 (e.g., rheumatological causes) and therefore referencing against all causes of painful shoulder may
387 represent the contribution of rotator cuff tear to the symptoms.

1
2
3 388
4 389 The definition of symptoms in previous studies varies widely with no consensus. The decision to use
5 390 the OSS was based upon its content, construct validity in relation to our research question, and
6 391 validation of use against other pain scores. Furthermore, dichotomisation of the scale at perfect vs.
7 392 non-perfect scores is not validated and may make results too sensitive. However, we ran a comparison
8 393 with 3-point change, as validated as clinically significant by the makers of the OSS, and there was no
9 394 statistical difference.

10 395

11 396 *Relationship to other studies*

12 397 This study has demonstrated similar prevalence figures to previous studies, but it is the first to use a
13 398 general population cohort that has been extensively characterised as representative of the western
14 399 world population.

15 400

16 401 Further studies have shown that the clinical presentation of rotator cuff tears varies and may or may
17 402 not be associated with symptoms^{17 22 23}. This general population cohort supports this with 48.4% of
18 403 full-thickness rotator cuff tears being asymptomatic. Prior to this, the only other population-based
19 404 study looking at symptom association with full-thickness tears was Yamamoto et al.³⁰ that
20 405 investigated symptom association with full-thickness tears using a mountain cohort in Japan. They
21 406 reported 34% of full-thickness tears to be symptomatic. However, unlike the current study, it was not
22 407 a general population cohort representative of western society. Furthermore, it was subject to selection
23 408 bias by removing any individuals with restricted shoulder movement or previous treatments.

24 409

25 410 Further studies have suggested that tear size affects the likelihood of symptoms. The current study
26 411 supports this with larger tears having a greater than 2-fold increase in relative risk of symptoms than
27 412 small tears^{17 22 23}. A previous study in the Washington series investigated by Yamaguchi et al²⁶,
28 413 reported development of symptoms in previously asymptomatic tendons in the context of a
29 414 contralateral symptomatic tear. However, this study was subject to selection bias as recruitment
30 415 occurred in a cohort actively being treated for contralateral symptomatic rotator cuff tears which may
31 416 have strengthened associations.

32 417

33 418 This is the first study that has looked at individuals as entities, rather than shoulders, and has
34 419 highlighted the effect the individual has on symptom presentation, which could include physical and
35 420 psychological factors unique to that individual – not solely the presence of tendon pathology on
36 421 imaging. It is also the first study to look at the impact on health services.

37 422

38 423

39 424 **Interpretation**

40 425 This study has shown that although patient reported pain on the Oxford Shoulder Score is associated
41 426 with rotator cuff tendon pathology, it is not related to the severity of structural pathology identified on
42 427 ultrasound imaging. The likelihood of pain also appears to be strongly dependent upon the individual
43 428 rather than simply the pathology. Consequently, clinicians should rely less on imaging findings to
44 429 explain the cause and severity of shoulder pain presentations. Furthermore, other drivers of shoulder
45 430 pain should be considered (e.g. pain sensitisation), and treatment be targeted on symptom
46 431 management rather than solely interventions to improve tendon pathology.

47 432

48 433 Investigation into the impact of musculoskeletal shoulder pain on the healthcare system revealed that
49 434 28.8% of people in this general population cohort sought consultation with their GP for shoulder pain,
50 435 a third of whom had a full thickness tear, and a third with at least one abnormality (no tear). This

1
2
3 436 study highlights the huge burden of shoulder pain on the healthcare system. Though, it does not
4 437 demonstrate causality of pain as is shown by the lack of symptoms in nearly half of cases and the lack
5 438 of correlation with the severity of pain and pathology. Nor does it show how the individual affects
6 439 pain presentation.
7
8 440

8 440

9 441 **Generalisability**

10 442 This epidemiological study that is generalisable to the UK population, demonstrates association but
11 443 not causality, and leaves unanswered questions as to what additional factors contribute to shoulder
12 444 pain. Particularly interesting is how individuals may or may not have painful shoulders irrespective of
13 445 the pathology. Further research into this could provide alternative targets to treatment methods, and
14 446 potentially reduce the cost of imaging modalities and surgical interventions.
15
16 447

16 447

17 448

18 448 **Conclusion**

19 449 In conclusion, this population-based study has demonstrated that full-thickness rotator cuff tears are
20 450 common affecting 22.1% of women over the age of 60, and tendon abnormalities affecting 59.4%.
21 451 Despite 41.7% of individuals with a full-thickness tear (48.4% of all full-thickness tears) being
22 452 asymptomatic, tendon abnormalities and tears are associated with pain. The likelihood, but not
23 453 severity of symptoms, increases with greater structural damage.
24
25 454

25 454

26 455

27 455 This high prevalence and association of symptoms results in a significant impact on primary care
28 456 health services, with 28.3% of this population having presented to a GP with shoulder pain. Of these a
29 457 third had a full-thickness tear and a third had an abnormal but non-torn tendon. Overall, 8.9% of this
30 458 cohort had seen their general practitioner with shoulder pain and a full-thickness tear, and 18.8% had
31 459 seen their general practitioner with an abnormal or torn tendon.
32
33 460

32 459

33 460

34 461

35 462

35 462 **REFERENCES**

- 36
37 1. Vos T, Abajobir AA, Abate KH, et al. Global, regional, and national incidence, prevalence,
38 and years lived with disability for 328 diseases and injuries for 195 countries, 1990-
39 2016: a systematic analysis for the Global Burden of Disease Study 2016. *The Lancet*
40 2017;390(10100):1211-59. doi: 10.1016/S0140-6736(17)32154-2
- 41
42 2. Urwin M, Symmons D, Allison T, et al. Estimating the burden of musculoskeletal disorders
43 in the community: the comparative prevalence of symptoms at different anatomical
44 sites, and the relation to social deprivation. *Annals of the Rheumatic Diseases*
45 1998;57(11):649-55. doi: 10.1136/ard.57.11.649 [published Online First: 1999/01/30]
- 46
47 3. Pope DP, Croft PR, Pritchard CM, et al. Prevalence of shoulder pain in the community: the
48 influence of case definition. *Annals of the Rheumatic Diseases* 1997;56(5):308-12.
49 doi: 10.1136/ard.56.5.308
- 50
51 4. Bunker T. Rotator cuff disease. *Current Orthopaedics* 2002;16:223-33. doi:
52 10.1054/cuor.2002.0257
- 53
54 5. Meislin RJ, Sperling JW, Stitik TP. Persistent shoulder pain: epidemiology,
55 pathophysiology, and diagnosis. *The American Journal of Orthopedics* 2005;34(12
56 Suppl):5-9. [published Online First: 2006/02/03]
- 57
58 6. Roquelaure Y, Ha C, Leclerc A, et al. Epidemiologic surveillance of upper-extremity
59 musculoskeletal disorders in the working population. *Arthritis Rheumatology*
60 2006;55(5):765-78. doi: 10.1002/art.22222 [published Online First: 2006/10/03]

- 1
2
3 7. Ng Man Sun S, Gillott E, Bhamra J, et al. Implant use for primary hip and knee
4 arthroplasty: are we getting it right first time? *The Journal of Arthroplasty*
5 2013;28(6):908-12. doi: 10.1016/j.arth.2012.11.012 [published Online First:
6 2013/03/20]
7
- 8 8. Hinsley H, Nicholls A, Daines M, et al. Classification of rotator cuff tendinopathy using
9 high definition ultrasound. *Muscles Ligaments Tendons Journal* 2014;4(3):391-7.
10 [published Online First: 2014/12/10]
11
- 12 9. Teefey SA, Rubin DA, Middleton WD, et al. Detection and quantification of rotator cuff
13 tears. Comparison of ultrasonographic, magnetic resonance imaging, and arthroscopic
14 findings in seventy-one consecutive cases. *The Journal of Bone and Joint Surgery*
15 *American Volume* 2004;86(4):708-16. [published Online First: 2004/04/08]
16
- 17 10. de Jesus JO, Parker L, Frangos AJ, et al. Accuracy of MRI, MR arthrography, and
18 ultrasound in the diagnosis of rotator cuff tears: a meta-analysis. *American Journal of*
19 *Roentgenology* 2009;192(6):1701-7. doi: 10.2214/ajr.08.1241 [published Online
20 First: 2009/05/22]
21
- 22 11. Naqvi GA, Jadaan M, Harrington P. Accuracy of ultrasonography and magnetic resonance
23 imaging for detection of full thickness rotator cuff tears. *International journal of*
24 *shoulder surgery* 2009;3(4):94-97. doi: 10.4103/0973-6042.63218
25
- 26 12. Smith TO, Back T, Toms AP, et al. Diagnostic accuracy of ultrasound for rotator cuff
27 tears in adults: a systematic review and meta-analysis. *Clinical Radiology*
28 2011;66(11):1036-48. doi: 10.1016/j.crad.2011.05.007 [published Online First:
29 2011/07/09]
30
- 31 13. Dinnes J, Loveman E, McIntyre L, et al. The effectiveness of diagnostic tests for the
32 assessment of shoulder pain due to soft tissue disorders: a systematic review. *Health*
33 *Technology Assessment* 2003;7(29):iii, 1-166. doi: 10.3310/hta7290 [published
34 Online First: 2003/10/22]
35
- 36 14. Ottenheim RP, Jansen MJ, Staal JB, et al. Accuracy of diagnostic ultrasound in patients
37 with suspected subacromial disorders: a systematic review and meta-analysis.
38 *Archives of Physical Medicine and Rehabilitation* 2010;91(10):1616-25. doi:
39 10.1016/j.apmr.2010.07.017 [published Online First: 2010/09/30]
40
- 41 15. Fehring EV, Sun J, VanOeveren LS, et al. Full-thickness rotator cuff tear prevalence
42 and correlation with function and co-morbidities in patients sixty-five years and
43 older. *Journal of Shoulder and Elbow Surgery* 2008;17(6):881-5. doi:
44 10.1016/j.jse.2008.05.039 [published Online First: 2008/09/09]
45
- 46 16. Milgrom C, Schaffler M, Gilbert S, et al. Rotator-cuff changes in asymptomatic adults.
47 The effect of age, hand dominance and gender. *The Journal of Bone & Joint Surgery*
48 *British Volume* 1995;77(2):296-8. [published Online First: 1995/03/01]
49
- 50 17. Moosmayer S, Smith HJ, Tariq R, et al. Prevalence and characteristics of asymptomatic
51 tears of the rotator cuff: an ultrasonographic and clinical study. *Journal of Bone and*
52 *Joint Surgery British Volume* 2009;91(2):196-200. doi: 10.1302/0301-
53 620x.91b2.21069 [published Online First: 2009/02/05]
54
- 55 18. Tempelhof S, Rupp S, Seil R. Age-related prevalence of rotator cuff tears in
56 asymptomatic shoulders. *Journal of Shoulder and Elbow Surgery* 1999;8(4):296-9.
57 [published Online First: 1999/09/03]
58
- 59 19. Reilly P, Macleod I, Macfarlane R, et al. Dead men and radiologists don't lie: a review of
60 cadaveric and radiological studies of rotator cuff tear prevalence. *Annals of The Royal*
College of Surgeons of England 2006;88(2):116-21. doi: 10.1308/003588406x94968
[published Online First: 2006/03/23]

- 1
2
3 20. Yamamoto A, Takagishi K, Osawa T, et al. Prevalence and risk factors of a rotator cuff
4 tear in the general population. *Journal of Shoulder and Elbow Surgery*
5 2010;19(1):116-20. doi: 10.1016/j.jse.2009.04.006 [published Online First:
6 2009/06/23]
7
- 8 21. Schibany N, Zehetgruber H, Kainberger F, et al. Rotator cuff tears in asymptomatic
9 individuals: a clinical and ultrasonographic screening study. *European Journal of*
10 *Radiology* 2004;51(3):263-8. doi: 10.1016/s0720-048x(03)00159-1 [published Online
11 First: 2004/08/06]
12
- 13 22. Yamaguchi K, Ditsios K, Middleton WD, et al. The demographic and morphological
14 features of rotator cuff disease. A comparison of asymptomatic and symptomatic
15 shoulders. *Journal of Bone and Joint Surgery American Volume* 2006;88(8):1699-
16 704. doi: 10.2106/jbjs.E.00835 [published Online First: 2006/08/03]
17
- 18 23. Mall NA, Kim HM, Keener JD, et al. Symptomatic progression of asymptomatic rotator
19 cuff tears: a prospective study of clinical and sonographic variables. *The Journal of*
20 *Bone and Joint Surgery American Volume* 2010;92(16):2623-33. doi:
21 10.2106/jbjs.I.00506 [published Online First: 2010/11/19]
22
- 23 24. Needell SD, Zlatkin MB, Sher JS, et al. MR imaging of the rotator cuff: peritendinous and
24 bone abnormalities in an asymptomatic population. *American Journal of*
25 *Roentgenology* 1996;166(4):863-7. doi: 10.2214/ajr.166.4.8610564 [published Online
26 First: 1996/04/01]
27
- 28 25. Sher JS, Uribe JW, Posada A, et al. Abnormal findings on magnetic resonance images of
29 asymptomatic shoulders. *The Journal of Bone and Joint Surgery American Volume*
30 1995;77(1):10-5. doi: 10.2106/00004623-199501000-00002 [published Online First:
31 1995/01/01]
32
- 33 26. Yamaguchi K, Tetro AM, Blam O, et al. Natural history of asymptomatic rotator cuff
34 tears: a longitudinal analysis of asymptomatic tears detected sonographically. *Journal*
35 *of Shoulder and Elbow Surgery* 2001;10(3):199-203. doi: 10.1067/mse.2001.113086
36 [published Online First: 2001/06/16]
37
- 38 27. Chandnani V, Ho C, Gerharter J, et al. MR findings in asymptomatic shoulders: a blind
39 analysis using symptomatic shoulders as controls. *Clinical Imaging* 1992;16(1):25-
40 30. doi: 10.1016/0899-7071(92)90085-n [published Online First: 1992/01/01]
41
- 42 28. Minagawa H, Yamamoto N, Abe H, et al. Prevalence of symptomatic and asymptomatic
43 rotator cuff tears in the general population: From mass-screening in one village.
44 *Journal of orthopaedics* 2013;10(1):8-12. doi: 10.1016/j.jor.2013.01.008 [published
45 Online First: 2014/01/10]
46
- 47 29. Harris JD, Pedroza A, Jones GL. Predictors of pain and function in patients with
48 symptomatic, atraumatic full-thickness rotator cuff tears: a time-zero analysis of a
49 prospective patient cohort enrolled in a structured physical therapy program.
50 *American Journal of Sports Medicine* 2012;40(2):359-66. doi:
51 10.1177/0363546511426003 [published Online First: 2011/11/19]
52
- 53 30. Yamamoto A, Takagishi K, Kobayashi T, et al. Factors involved in the presence of
54 symptoms associated with rotator cuff tears: a comparison of asymptomatic and
55 symptomatic rotator cuff tears in the general population. *Journal of Shoulder and*
56 *Elbow Surgery* 2011;20(7):1133-7. doi: 10.1016/j.jse.2011.01.011 [published Online
57 First: 2011/04/02]
58
- 59 31. Arden NK, Griffiths GO, Hart DJ, et al. The association between osteoarthritis and
60 osteoporotic fracture: the Chingford Study. *The British Journal of Rheumatology*

- 1
2
3 1996;35(12):1299-304. doi: 10.1093/rheumatology/35.12.1299 [published Online
4 First: 1996/12/01]
5
6 32. Hart DJ, Mootoosamy I, Doyle DV, et al. The relationship between osteoarthritis and
7 osteoporosis in the general population: the Chingford Study. *Annals of the Rheumatic*
8 *Diseases* 1994;53(3):158-62. doi: 10.1136/ard.53.3.158 [published Online First:
9 1994/03/01]
10
11 33. Hart DJ, Spector TD. The relationship of obesity, fat distribution and osteoarthritis in
12 women in the general population: the Chingford Study. *Journal of Rheumatology*
13 1993;20(2):331-5. [published Online First: 1993/02/01]
14
15 34. Dawson J, Fitzpatrick R, Carr A. Questionnaire on the perceptions of patients about
16 shoulder surgery. *The Journal of Bone and Joint Surgery British Volume*
17 1996;78(4):593-600. [published Online First: 1996/07/01]
18
19 35. Dawson J, Rogers K, Fitzpatrick R, et al. The Oxford shoulder score revisited. *Archives of*
20 *Orthopaedic and Trauma Surgery* 2009;129(1):119-23. doi: 10.1007/s00402-007-
21 0549-7 [published Online First: 2008/01/10]
22
23 36. Murphy RJ, Daines MT, Carr AJ, et al. An independent learning method for orthopaedic
24 surgeons performing shoulder ultrasound to identify full-thickness tears of the rotator
25 cuff. *The Journal of Bone and Joint Surgery American Volume* 2013;95(3):266-72.
26 doi: 10.2106/jbjs.K.00706 [published Online First: 2013/02/08]
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

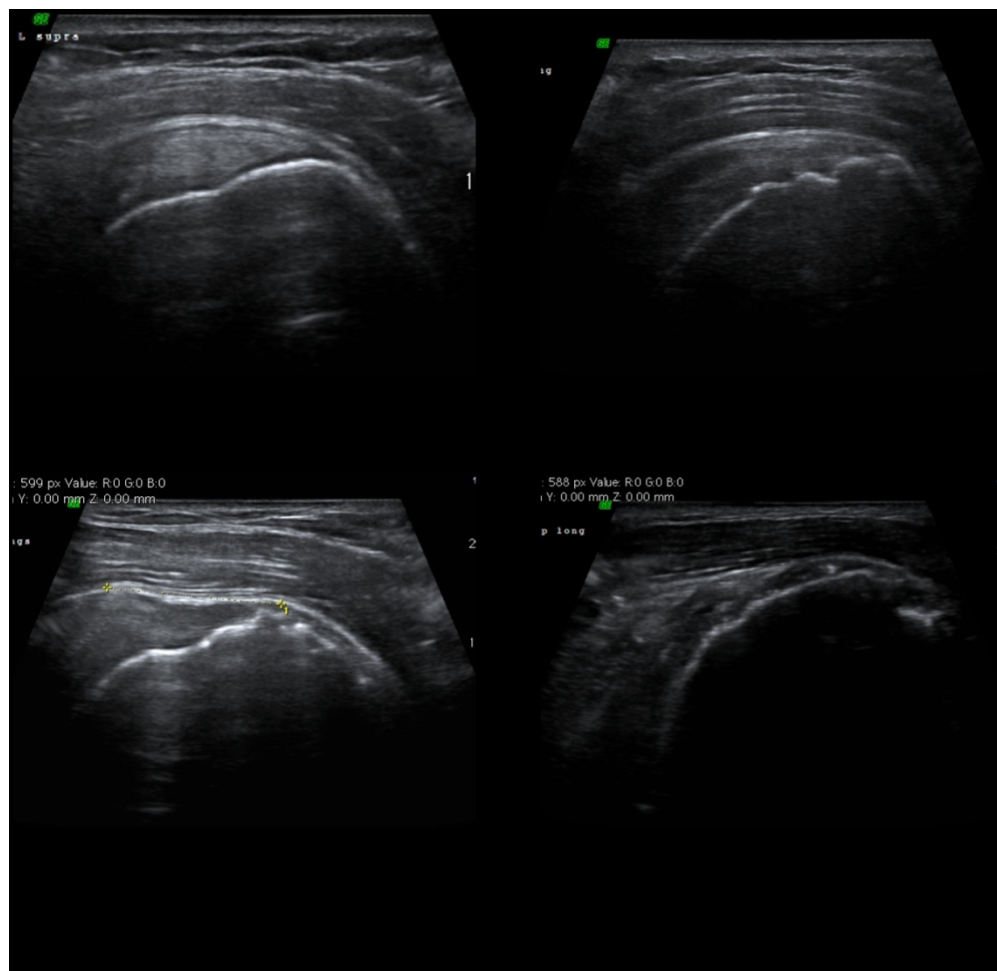
Figures

Figure 1: Tendon classification on ultrasound

Figure 1 caption: (i) normal tendon: normal homogenous appearance throughout with no abnormality at the enthesis; (ii) abnormal tendon: loss of homogenous appearance and abnormal ragged enthesis +/- enlarged fluid-filled bursa or partial thickness tear; (iii) full thickness tear (0-2.5cm): lucent patch through the full thickness of the tendon with tear size defined as its width in the sagittal plane (iv) full-thickness tears (>2.5cm): Evidence of large defect or no evidence of tendon tissue present.

Figure 2: Distribution of symptoms across each tendon group

For peer review only



Tendon classification on ultrasound: (i) normal tendon: normal homogenous appearance throughout with no abnormality at the enthesis; (ii) abnormal tendon: loss of homogenous appearance and abnormal ragged enthesis +/- enlarged fluid-filled bursa or partial thickness tear; (iii) full thickness tear (0-2.5cm): lucent patch through the full thickness of the tendon with tear size defined as its width in the sagittal plane (iv) full-thickness tears (>2.5cm): Evidence of large defect or no evidence of tendon tissue present.

106x102mm (330 x 330 DPI)

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

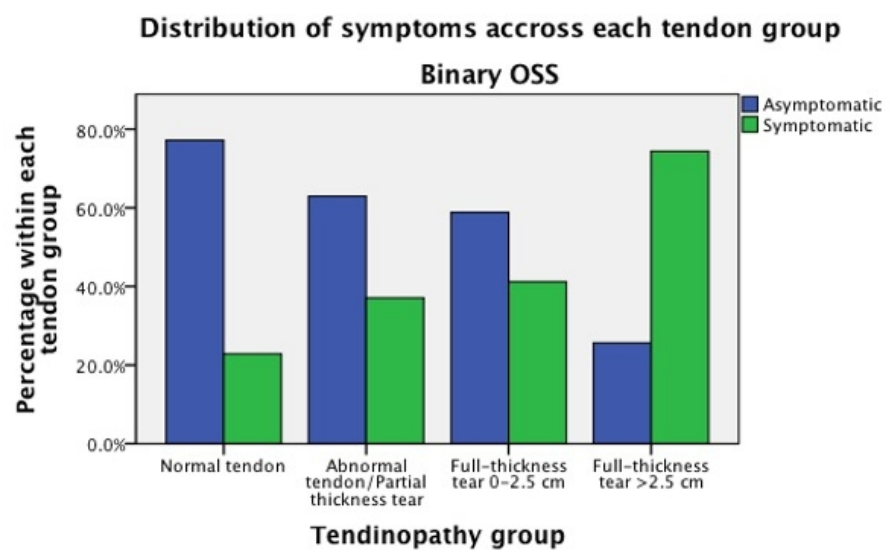


Figure 2. Distribution of symptoms across each tendon group

116x68mm (144 x 144 DPI)

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No.	Recommendation	Page No.	Relevant text from manuscript
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	Page 1 -	title of the manuscript
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	Page 3	
Introduction				
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Page 4 -	line 128-153
Objectives	3	State specific objectives, including any prespecified hypotheses	page 4	lines 150-154
Methods				
Study design	4	Present key elements of study design early in the paper	Page 4 -	lines 165-176
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Page 4 -	lines 165-176
Participants	6	(a) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	Pages -	lines 165-176
		<i>Case-control study</i> —Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls		
		<i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants		
		(b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed		
		<i>Case-control study</i> —For matched studies, give matching criteria and the number of controls per case		
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Page 5 -	lines 182-198
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Page 5 -	lines 181-198
Bias	9	Describe any efforts to address potential sources of bias	Page 10 -	lines 351-393
Study size	10	Explain how the study size was arrived at	Page 4 -	Lines 174-177

Continued on next page

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46

Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Page 5-6 - lines 207-236
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding (b) Describe any methods used to examine subgroups and interactions (c) Explain how missing data were addressed (d) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed <i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed <i>Cross-sectional study</i> —If applicable, describe analytical methods taking account of sampling strategy (e) Describe any sensitivity analyses	SECTION 12 - Page 5-6 - lines 207-236
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed (b) Give reasons for non-participation at each stage (c) Consider use of a flow diagram	Page 6 - lines 239-246
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders (b) Indicate number of participants with missing data for each variable of interest (c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)	Page 6 - lines 239-246
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time <i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure <i>Cross-sectional study</i> —Report numbers of outcome events or summary measures	Pages 6-9
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included (b) Report category boundaries when continuous variables were categorized (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	Results tables, pages 6-9 - lines 248-325

Continued on next page

Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Not applicable
Discussion			
Key results	18	Summarise key results with reference to study objectives	Page 9- lines 328-351
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	Page 10 - 356-392
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Page 11 - lines 422-437
Generalisability	21	Discuss the generalisability (external validity) of the study results	Page 11 - lines 440-445
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Page 2 - lines 50-53

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.