**PEER REVIEW HISTORY**

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (see an example) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below. Some articles will have been accepted based in part or entirely on reviews undertaken for other BMJ Group journals. These will be reproduced where possible.

**ARTICLE DETAILS**

<table>
<thead>
<tr>
<th>TITLE (PROVISIONAL)</th>
<th>Patient accounts of medication use in early rheumatoid arthritis from symptom onset to early post diagnosis</th>
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<tr>
<td>AUTHORS</td>
<td>Townsend, Anne; Backman, Catherine; Adam, Paul; Li, Linda</td>
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**VERSION 1 - REVIEW**

<table>
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<tr>
<th>REVIEWER</th>
<th>Dr Karim Raza, PhD FRCP</th>
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<tr>
<td></td>
<td>Reader in Clinical Rheumatology &amp; Honorary Consultant Rheumatologist</td>
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<td></td>
<td>University of Birmingham and Sandwell &amp; West Birmingham Hospitals NHS Trust, UK</td>
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<td>I have no competing interests in the context of this review.</td>
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<td>REVIEW RETURNED</td>
<td>21-Oct-2012</td>
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**THE STUDY**

Townsend and colleagues report data on perspectives on medication use from a large qualitative study in patients with rheumatoid arthritis prior to and shortly after diagnosis. The impact of over the counter medication on help seeking and patients’ views on prescribed medicines in the early phases of RA are important issues within Rheumatology. Furthermore, as highlighted by the authors, these issues have broader significance and will be relevant to other health conditions. Explanations regarding my responses to specific questions in the Reviewer’s proforma where I have indicated a deficiency in the manuscript are as follows:

Re: Are the patients representative of actual patients the evidence might affect?

Women are over represented and all patients are English speaking and of Caucasian origin. However, these have been highlighted as study limitations by the authors themselves.

Re: Are the participants adequately described, their conditions defined, and the inclusion and exclusion criteria described?

The authors have highlighted that patients were recruited within one year of an RA diagnosis. Are data available on the duration of symptoms prior to interview? For many, delays in seeking help will mean that they will have had clinically apparent RA for much longer than one year and an indication of prior symptom duration would be helpful.

The manuscript details that all participants were diagnosed with RA. Was this a clinical diagnosis or was there a requirement for
participants to fulfil classification criteria for RA (e.g. the 1987 ACR criteria)?

Although I recognise that this is qualitative research, some additional quantitative data on the characteristics of their subjects would be helpful. For example, we are told that participants were “aged 30s-70s”. It is possible that almost all were in their early 30s and only very few in their late 70s. Given that age may well have an impact on many of the issues being addressed it would be helpful to have some more data on the ages of the participants for example what was the median age?

Re: Are the statistical methods described?

This is not applicable to this qualitative study and was not a relevant question to ask in the context of this manuscript.

Re: Is the standard of written English acceptable for publication?

There are spelling, stylistic and grammatical errors throughout, and the authors should review the manuscript carefully from these perspectives. Examples include: (a) The phrase “Over the counter (OTC)” is used twice on p4. After the first explanation of the abbreviation the abbreviation can be used by itself. (b) The abbreviation DMARD is not explained before it is first use (p5). (c) “via family members’ experiences” or web-based information” (p10) should read “via family members’ experiences or web-based information”. (d) The following words are spelt incorrectly “diarreah” (p8), “Caucasion” (p6). (e) The references are inconsistently formatted.

Re: Are the references up to date and relevant? (If not, please provide details of significant omissions below.)

There is very little reference in this paper to the existing literature on patients’ perspectives on medication for RA. Although I recognise that much of the existing literature does not focus on the earliest phases of RA, and an interesting and an important aspect of the current manuscript is that it does focus on this phase, the authors may find it helpful to interpret their results in the context of other literature in this area. Examples of publications they may wish to consider are:


GENERAL COMMENTS

Additional comments for the authors:

1. The authors state that “RA symptoms include pain and inflammation...” (p5). “Inflammation” is not a “symptom”.

2. The authors state that “Combination therapy is standard care...” (p5). “Combination therapy” should be defined more clearly.

3. The authors state that “ sufferers...” (p5). “Sufferers” should be defined more clearly.

4. The authors state that “The...” (p5). “The...” should be defined more clearly.

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50. The authors state that “ The...” (p5). “ The...” should be defined more clearly.
which involves DMARDs, NSAIDs and analgesics” (p5). Within the Rheumatological field the term “combination therapy” tends to be applied to combination DMARD therapy and to avoid confusion I suggest the authors use the term in this way. If they want to talk about the use of DMARDs with other RA therapeutics, they should refer for example to “Combinations of DMARDs, NSAIDs and analgesics”. It should be highlighted that it remains controversial as to whether a combination of DMARDs does actually represent optimal care for newly presenting RA patients. Although current UK guidance from the National Institute of Health and Clinical Excellence (NICE) does advocate combination DMARD therapy, recent EULAR guidance suggests the use of a single DMARD (methotrexate unless contraindicated) as first line therapy.

3. The authors highlight that the “analysis formed part of a wider study on the experience of help seeking in early rheumatoid arthritis” (p5). It is not clear whether the exploration of issues related to medication use was one of several a priori aims of the “wider study” or whether the “wider study” had an entirely different set of aims and that any information on medication use was collected whilst addressing that different set of aims. This is important as it may have influenced the extent it which issues related to medication use were specifically probed for.

4. Did interviews continue until thematic saturation was reached in the context of “medication use”?

5. What do the authors mean by “No apriori themes or codes were identified” (p7)?

6. I do not understand what the authors mean by the word “Contradictions” in the context of their subheading “Contradictions: The e-patient, help seeking and shared decision making”.

7. The issue of adherence to prescribed medicine is important in all chronic diseases and the authors recognise this in their Introduction. Given this, it is surprising that there are very few data in the Results section in relation to adherence to prescribed medication. Was this topic not included in the topic guide? It would certainly seem a relevant area to ask questions about in the context of “medication use”.

REVIEWER
Dr. Heidi Lempp 22.10.12
Medical Sociologist in Rheumatology
I have no competing interests.

THE STUDY
I have read with interest the paper, as it is an important one in the care of patients with RA, and have the following comments:
* it seems to me that the title needs to be re-considered, as much of the content states/mentions OTC medication. I wonder whether this was the focus of the wider study from which the patients where recruited from?
* line 40 p1. needs a reference or is the statement from Reference 1? I was not clear.
*P2 line 37-49: are the sentences stated objectives of the study or are they part of the interview schedule, it was unclear to me.
*line 56: can you provide examples pl of chronic illnesses that share
The phrase chroniic illness is commonly now replaced by long-term illness, at least in Europe.

*p.5 line 25: 'current evidence supports use of combined DMARDs', this is true, however the authors seem to relate combination therapy to DMARDs and analgesia and NSAIDS. Combination therapy related to combined DMARDs or DMARDs and biologic. Mentioning analgesia in this context therefore is confusing and not correct in my view.

Participants and method
*) Interviews took 1-2 hours, why was there such a discrepancy between the interviewees, can the authors explain this please
* many different interviewers were used for the study, this can cause differences in the quality of the data, as each person comes with a different background, which will reflect on the data quality. This may also be the reason why the interview duration varied so greatly? Can authors pl comment on this.
* who did the transcribing?
* how where the field notes used in the data analysis?
* how were the second interviews incorporated in the data analysis?

Data analysis
* what kind of data analysis was applied, that was not stated, was it a combined analysis e.g. content and discourse analysis, or a single analysis, please state.
* what validity checks were implanted, apart from inclusion of deviant data? I was surprised for example that no external qualitative researcher was asked to check the codes that were identified by two of the authors. External researchers can often shed new ideas for the codes, as they have not been involved in the study. Or initial findings can be presented to the clinical team to see if they resonate with their knowledge and experiences. The use of single counting would be very helpful here, it is very unclear how 'strong' the data was, as authors refer to 'most', 'only few', 'majority described', 'several'. This seems vague to me and single counting would make the data more robust, e.g. 15/37 patients. At the moment the data is not convincing. In addition the authors added many single accounts as examples in the subheadings of the result section. I did not find this very helpful, as it distracted from the actual finds in the boxes and as a reader I was lost what the findings actually were.
* the phrase 'agressive treatment' in RA, is now replaced by 'intensive treatment'.

Discussion:
* please state here that the study sample was not representative, as patients from different ethnic backgrounds were not included, or some comments need to be made in the discussion section.
*I am not able to make more comments in the discussion section, as the result section as it stands is unclear and not rigorous enough.

GENERAL COMMENTS
I hope the feedback is seen as helpful/constructive rather than negative.

VERSION 1 – AUTHOR RESPONSE

Reviewer 1

The authors have highlighted that patients were recruited within one year of an RA diagnosis. Are data available on the duration of symptoms prior to interview? For many, delays in seeking help will mean that they will have had clinically apparent RA for much longer than one year and an indication of prior symptom duration would be helpful.
RESPONSE – Good point. Self-reported duration of symptoms is now included in TABLE 1.

The manuscript details that all participants were diagnosed with RA. Was this a clinical diagnosis or was there a requirement for participants to fulfill classification criteria for RA (e.g. the 1987 ACR criteria)?

RESPONSE – The RA diagnosis was reported by participants as confirmed by either the rheumatologist or GP, for all but 2 participants, one of whom had complex and multiple conditions and was undergoing multiple tests with different specialists. This has now been identified in the paper as ‘self-reported’ diagnosis.

Although I recognise that this is qualitative research, some additional quantitative data on the characteristics of their subjects would be helpful. For example, we are told that participants were “aged 30s-70s”. It is possible that almost all were in their early 30s and only very few in their late 70s. Given that age may well have an impact on many of the issues being addressed it would be helpful to have some more data on the ages of the participants for example what was the median age?

RESPONSE – good point – SEE TABLE we have identified the age range of each participant.

Re: Is the standard of written English acceptable for publication?
There are spelling, stylistic and grammatical errors throughout, and the authors should review the manuscript carefully from these perspectives. Examples include:
(a) The phrase “Over the counter (OTC)” is used twice on p4. After the first explanation of the abbreviation the abbreviation can be used by itself. (b) The abbreviation DMARD is not explained before it is first use (p5). (c) “via family members’ experiences’ or web-based information” (p10) should read “via family members’ experiences or web-based information”. (d) The following words are spelt incorrectly “diarreah” (p8), “Caucasion” (p6).

RESPONSE – We have aimed to correct all errors.

(e) The references are inconsistently formatted.
Re: Are the references up to date and relevant? (If not, please provide details of significant omissions below.)
There is very little reference in this paper to the existing literature on patients’ perspectives on medication for RA. Although I recognise that much of the existing literature does not focus on the earliest phases of RA, and an interesting and an important aspect of the current manuscript is that it does focus on this phase, the literature in this area. Examples of publications they may wish to consider are:

RESPONSE – Thank you for these helpful references which have been cited in the revised manuscript. Other references have also been added. The reference list has been consistently formatted.

1. Page 5. Inflammation is not a symptom. RESPONSE – This has been corrected.
2. Combination therapy needs clarification. The phrasing has been changed to remove ambiguity. The discussion of combined therapy has not been included.

3. The authors highlight that the “analysis formed part of a wider study on the experience of help seeking in early rheumatoid arthritis” (p5). It is not clear whether the exploration of issues related to medication use was one of several a priori aims of the “wider study” or whether the “wider study” had an entirely different set of aims and that any information on medication use was collected whilst addressing that different set of aims. This is important as it may have influenced the extent it which issues related to medication use were specifically probed for.

RESPONSE - We have inserted more detail about the wider study, although given word count limitations it is still brief. We also include the interview topic guide as supplementary data.

4. Did interviews continue until thematic saturation was reached in the context of “medication use”?

RESPONSE – No. Although this is a relatively large data set (38 interviews, 19 follow up/verification interviews), we found no new themes emerging as we examined the interviews. However, this was probably because people were asked in very broad ways to describe their experiences and it was not possible to probe in detail all aspects of medication use e.g. the process of shared decision making; details of internet-use and details of flexible medication use, with all participants, because this emerged from later data analysis, not the primary research question on help-seeking. This emergent theme warrants further examination which is mentioned in the Discussion.

5. What do the authors mean by “No apriori themes or codes were identified” (p7)

RESPONSE – We have changed the wording to clarify.

6. I do not understand what the authors mean by the word “Contradictions” in the context of their subheading “Contradictions: The e-patient, help seeking and shared decision making”.

RESPONSE – We have taken out this section; we could not do this theme (e-patient/internet use) justice given the word count limit and suggestions to clarify other important themes.

7. The issue of adherence to prescribed medicine is important in all chronic diseases and the authors recognise this in their Introduction. Given this, it is surprising that there are very few data in the Results section in relation to adherence to prescribed medication. Was this topic not included in the topic guide? It would certainly seem a relevant area to ask questions about in the context of “medication use”.

RESPONSE – We have revised the presentation of ambivalence and adherence. In order to focus on this theme we have taken out the theme on multi-morbidity. Adherence was not specifically addressed in the topic guide, which addressed the primary research question related to help-seeking. The overarching aim at study inception was not about medication use; however, we wanted to get at what was important to patients and their experiences, and the medication issues presented in this manuscript arose spontaneously in response to questions about managing symptoms. We agree with the reviewer that adherence is an important area but are limited to presenting what was discovered in this ‘second look’ at an emergent theme.

Reviewer 2 (qualitative sociologist)

1. It seems to me that the title needs to be re-considered, as much of the content states/mentions OTC medication. I wonder whether this was the focus of the wider study from which the patients where recruited from?

RESPONSE: The title has been revised.
2. line 40 p1. needs a reference or is the statement from Reference 1? I was not clear.
RESPONSE – This has been corrected (part of reference 1).

3. P2 line 37-49: are the sentences stated objectives of the study or are they part of the interview schedule, it was unclear to me.
RESPONSE – This has been clarified as themes which emerged from the study.

4. line 56: can you provide examples pl of chronic illnesses that share similar symptoms to RA.
RESPONSE – have reworded and included a disease in study limitations (multiple sclerosis).

5. the phrase chronic illness is commonly now replaced by long-term illness, at least in Europe
RESPONSE – We have retained chronic illness because it is the term used in our health care system (the location of the study) but are amenable to the Editor changing this terminology if better suited to the Journal.

6. p.5 line 25: ‘current evidence supports use of combined DMARDS’, this is true, however the authors seem to relate combination therapy to DMARDS and analgesia and NSAIDs. Combination therapy related to combined DMARDS or DMARDS and biologic.
Mentioning analgesia in this context therefore is confusing and not correct in my view.
RESPONSE – Participants were not necessarily referring to “combination therapy” but were describing a combination of drugs. We have clarified this in the revised manuscript. (Reviewer 1 made a similar recommendation).

Participants and Methods

1. Interviews took 1-2 hours, why was there such a discrepancy between the interviewees, can the authors explain this please.
RESPONSE: The interviews were based on a topic guide. Participants prioritized what they wanted to say, and we used probes and prompts. Most interviews took 60-90 minutes; the range is wide which reflects the interest and stories shared by the participants/informants. Further, some participants took a stretch break and others had appointments or commitments that limited the time they were able to volunteer for an interview. For those who were interviewed for longer, they gave examples like: I want my story to be heard. They had made notes, and wanted to share their experiences.

2. Many different interviewers were used for the study, this can cause differences in the quality of the data, as each person comes with a different background, which will reflect on the data quality. This maybe also the reason why the interview duration varied so greatly? Can authors pl comment on this.
RESPONSE – This is a very worthwhile point to raise. Most interviews were conducted by experienced qualitative researchers AT and PA. We did not see a trend re: interview length related to interviewer. We intentionally included other investigators as interviewers to enhance their understanding of the data gathering process and verify the fit between the interview guide and the conceptualization of the study and data analysis. While we recognize the interviewer is the research instrument we built in safeguards to ensure the integrity of the data and the findings as far as possible (training interviewers, did not analyze responses to leading questions, recognized a lack of detailed description). All had experience of interviews in clinical settings, observed interviews by AT or PA in this study, and all
interviews were read and annotated by PA and AT to offer comments insights and further questioning. We have commented on the possible limitation of multiple interviewers in the Discussion.

3. Who did the transcribing?
RESPONSE: An experienced, out of house transcriber was used, who had worked with us on previous studies, and closely followed our guidelines for transcribing e.g. verbatim, pauses, laughter.

4. How were the field notes used in the data analysis?
RESPONSE: Field notes (were organized into sections: Physical layout of room; the gist of the interview; how it had gone; the mood of the interviewer). This helped with reflexivity, but field notes were not coded as data. They were of particular importance to identify the gist of the interview to guard against going with first impressions which may override more nuanced understandings. The use of field notes is briefly cited in the revised text (due to limits on word count).

5. How were the second interviews incorporated in the data analysis?
RESPONSE: The 19 follow-up interviews were used to verify our interpretation of the in-depth/in-person interviews, and for elaboration and clarification. All interviews (initial and follow-up) were treated the same way in the data analysis: read, re-read, coded, and provided illustrative quotes in support of the themes.

Data analysis
1. What kind of data analysis was applied, that was not stated, was it a combined analysis e.g. content and discourse analysis, or a single analysis, please state.
RESPONSE – Analysis was guided by grounded theory (constant comparison), but it is largely a thematic, content analysis. This manuscript shares the interpretation of one emergent area from the larger/primary study, a single content area. This has been clarified in the Method.

2. What validity checks were implemented, apart from inclusion of deviant data? I was surprised for example that no external qualitative researcher was asked to check the codes that were identified by two of the authors. External researchers can often shed new ideas for the codes, as they have not been involved in the study. Or initial findings can be presented to the clinical team to see if they resonate with their knowledge and experiences. The use of single counting would be very helpful here, it is very unclear how 'strong' the data was, as authors refer to 'most', 'only few', 'majority described', 'several'. This seems vague to me and single counting would make the data more robust, e.g. 15/37 patients. At the moment the data is not convincing. In addition the authors added many single accounts as examples in the subheadings of the result section. I did not find this very helpful, as it distracted from the actual finds in the boxes and as a reader I was lost what the findings actually were.

RESPONSE – The revision of the manuscript has focused on the topic of medication use, deleted some distractions in the findings. Therefore, more direct data (quotes) have been inserted to support the stated findings. Supplementary files have been added. While we respect your opinion that counts would be more convincing or robust, we respectfully disagree – we propose it is the quality of the description and relative importance to individuals that adds robustness to a qualitative study and that numerical counts or tallies can be misleading (consistent with Morse, J. (2007). Qualitative researchers don’t count. Qualitative Health Research, 17, 287). However, we have aimed to clarify and improve the reporting of findings.
the phrase ‘aggressive treatment’ in RA, is now replaced by ‘intensive treatment’.
RESPONSE – We are quoting the participant perspectives when using ‘aggressive treatment’ and it appears that they have heard/learned that term in the experiences shared with us. We acknowledge that ‘intensive treatment’ might be used by professionals, but this paper reports patient perspectives.

Discussion:
* please state here that the study sample was not representative, as patients from different ethnic backgrounds were not included, or some comments need to be made in the discussion section.
RESPONSE – This was stated as a study limitation. Please see Discussion.

*I am not able to make more comments in the discussion section, as the result section as it stands is unclear and not rigorous enough.
RESPONSE – The Results section has been revised for clarity; subsequently the Discussion was revised to follow. Because we now focus on fewer main themes the report of findings should be more convincing.

**VERSION 2 – REVIEW**

<table>
<thead>
<tr>
<th>REVIEWER</th>
<th>Dr Karim Raza, PhD FRCP</th>
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<tbody>
<tr>
<td></td>
<td>Reader in Clinical Rheumatology &amp; Honorary Consultant Rheumatologist</td>
</tr>
<tr>
<td></td>
<td>University of Birmingham &amp; Sandwell &amp; West Birmingham Hospitals NHS Trust, UK.</td>
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<tr>
<td>REVIEW RETURNED</td>
<td>05-Dec-2012</td>
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**THE STUDY**

Statistical methods are not relevant to this research

The standard of English needs to be improved. There remain multiple typographical, stylistic and grammatical errors e.g. [1] “This study highlights how people use in early RA” (conclusion of the abstract)- presumably the word “medication” should be included in this sentence. [2] “self-regulat” (p10). [3] “a GP appointment considered a hassle significantly, ...” (p10). There are many other examples. The manuscript still needs to be corrected from this perspective.

**RESULTS & CONCLUSIONS**

The Results section has been divided into 2 sections: [1] “Paradox: pre-diagnosis use of over the counter (OTC) medicines”; [2] “Ambivalence: post-diagnosis prescribed medication use”. This split makes clear sense to me and makes this version of the paper much easier to follow than the original version. However within the first section there appears to be a subheading “Self-assessing symptoms and regulating OTC medicine intake”. It is not clear to me how the data that appear under this subheading differ from those in the rest of the first section and thus what the point of having this subheading is.

Table 1. The ages are presented in a very unusual way. Some are presented as decades (e.g. 50s) some as a span or 20 years (60s-70s) and some as a longer span (30s-50s). Did the authors determine the patients’ actual age? If so a consistent approach to reporting it should be used.
Table 1. Data regarding the duration from symptom onset to seeking help are, for some individuals, very surprising. For “Smokie Jean” (aged 50s -60s) for example this interval is reported as 40 years. Thus according to this Table it is possible that her RA symptoms began at the age of 10. This is highly unlikely. The authors need to clarify that data in this column relate to self reported “symptom onset” rather than the date of symptom onset determined in discussion with a health care professional experienced in the assessment of RA. Determining which symptoms mark the onset of RA is notoriously difficult - some patients will date the onset of RA to episodes such as a period of mechanical back pain or osteoarthritis pain in the DIP joint which are unlikely to represent the onset of RA.

GENERAL COMMENTS
This is the second opportunity I have had to review this manuscript. The areas covered by the research are of interest to the Rheumatological community and have broader implications for care pathways for patients with non-rheumatological diagnoses. The manuscript has been improved from the original version. The majority of my comments are detailed under the specific subheadings above. In addition, I have the following two minor questions:
1. What is the difference between a “causal co-morbidity” and an “adverse reaction” or “side effect” (p3)? Is the term “causal co-morbidity” not superfluous?
2. What does the phrase “the early RA diagnosis be questionable” mean (p9)?

REVIEWER
Dr. Heidi Lempp
Medical Sociologist
King's College London, School of Medicine
UK
I have no competing interests.

REVIEW RETURNED
06-Dec-2012

THE STUDY
I was unclear about the pilot study. The authors stated that a pilot study was carried out, but not how many patients were included and whether the changes have been made for the interview schedule.

RESULTS & CONCLUSIONS
The authors have addressed very well most of the comments I have made, and I am grateful. However, I do not agree with their comments re. not using numbers in qualitative research. In my view as stated before the single counting would make the results much more robust, the phrases used e.g. most conveyed, the majority, only a few etc. are too vague, and made the results less convincing and plausible for me. Only providing accounts from a small number of interviewees is not enough in my view, a single counting would include all participants. Single counting has been endorsed by other qualitative researchers that can be found in the literature, e.g. Seale C; Silverman D.
I will need to leave it with the editorial team to decide whether the result section is robust for the online journal.

VERSION 2 – AUTHOR RESPONSE

Reviewer 1 (clinician)

1. The standard of English needs to be improved. There remain multiple typographical, stylistic and grammatical errors e.g. [1] “This study highlights how people use in early RA” (conclusion of the
ababstract)- presumably the word “medication” should be included in this sentence. [2] “self-regulat”
(p10). [3] "a GP appointment considered a hassle ignificantly, ..." (p10). There are many other
examples. The manuscript still needs to be corrected from this perspective.

RESPONSE - The manuscript has been edited and amendments made throughout in track changes.
No substantive changes have been made.

2. Within the first section there appears to be a subheading “Self-assessing symptoms and regulating
OTC medicine intake”. It is not clear to me how the data that appear under this subheading differ from
those in the rest of the first section and thus what the point of having this subheading is.

RESPONSE – This point is well taken but we have kept the structure. We have separated the ‘OTC
medication use’ section into two sub-sections because we feel it is important to identify two different
but overlapping dimensions of OTC medication use. The first sub-section’s focus is the participants’
descriptions of how medications helped them function and how they relied heavily on medication to
fulfill roles. The second sub-section focuses more on the practical strategies of self-regulating,
involved in using OTC medications. So the practical strategies of working out optimum effect/trial and
error of taking different types/strengths/amounts/combinations of medications. Because of the
importance of the context in which people self-regulate, we recognize that a few quotes overlap.

3. Table 1. The ages are presented in a very unusual way. Some are presented as decades
(e.g. 50s) some as a span or 20 years (60s-70s) and some as a longer span (30s-50s).
Did the authors determine the patients’ actual age? If so a consistent approach to
reporting it should be used.

RESPONSE – This point is well taken, and we have amended the table to make consistent. The age
of participants was not asked systematically. However, during the interviews some participants
referred to their exact age, some gave their approximate age, and other ages were assessed based
on the content of the interviews. Although we have the exact age of several, to keep reporting
consistent, we have re-checked the interviews and field-notes and the table now reports the age
decade. Three of the 38 participants’ ages were estimated by the interviewer as identified on the
table.

4. The authors need to clarify that data in this column relate to self reported “symptom onset” rather
than the date of symptom onset determined in discussion with a health care professional experienced
in the assessment of RA. Determining which symptoms mark the onset of RA is notoriously difficult -
some patients will date the onset of RA to episodes such as a period of mechanical back pain or
osteoarthritis pain in the DIP joint which are unlikely to represent the onset of RA.

RESPONSE – We thank the reviewer for making this point. We have identified self-reporting, for
clarification purposes, in the table.

5. I have the following two minor questions:
What is the difference between a “causal co-morbidity” and an “adverse
reaction” or “side effect” (p3)? Is the term “causal co-morbidity” not superfluous?

RESPONSE – We thank the reviewer for pointing this out and have omitted the phrase ‘causal co-
morbidity”

6. What does the phrase “the early RA diagnosis be questionable” mean (p9)?
RESPONSE - This phrase has now been moved to the discussion and elaborated upon. We suggest
that because so many of the participants described long term symptoms, they may (or may not) have
had RA for months or perhaps years prior to being diagnosed. Although, as the reviewer has pointed out determining which symptoms mark the onset of RA is notoriously difficult, we feel our findings highlight questions around how ‘early’ was ‘early RA’ for many of the participants in our study.

Reviewer 2 (qualitative sociologist)

1. I was unclear about the pilot study. The authors stated that a pilot study was carried out, but not how many patients were included and whether the changes have been made for the interview schedule.

RESPONSE: We have identified number of participants in the Pilot and stated no main changes to interview guide.

2. I do not agree with their comments re. not using numbers in qualitative research. In my view as stated before the single counting would make the results much more robust, the phrases used e.g. most conveyed, the majority, only a few etc. are too vague, and made the results less convincing and plausible for me. Only providing accounts from a small number of interviewees is not enough in my view, a single counting would include all participants. Single counting has been endorsed by other qualitative researchers that can be found in the literature, e.g. Seale C; Silverman D.

RESPONSE: We thank the reviewer for elaborating on this point. We want to clarify that we did not state and do not believe that numbers are not relevant in qualitative research per se, though some may make this claim. We stated “we propose it is the quality of the description and relative importance to individuals that adds robustness to a qualitative study and numerical counts and tallies can be misleading.” Our position reflects Silverman: “It is usually mistaken to count simply for the sake of counting. Without a theoretical rationale behind the tabulated categories, counting only gives a spurious validity to research “ (p184, Silverman 2000, Doing Qualitative Research: A Qualitative Handbook, Sage, London). Likewise, Seale notes counting can help rigor in qualitative research (same volume P157), but he does not maintain that counting is a requirement to ensure robust or rigorous research. We point out that it is easy to count frequencies in response to a direct question, but it is a little misleading to ‘count’ someone as in agreement with an interpretive stance when they alluded to behavior/attitudes but did not indicate how important/significant/extension while others described it in a way that is highly salient, while others may not discuss a topic which emerged in an in-depth interview, because the interview followed another path, yet all would carry equal weight in a frequency count. We agree that numbers can be used in qualitative research (in particular circumstances e.g. in more semi-structured interviews where all participants are asked the same questions). We used a topic guide, and listened to the priorities of the participants, the probes and prompts meant that not all participants discussed the same topics to the same degree. We feel that counting may miss the nuanced understandings of accounts. We add that robust research can be sought in the process of research e.g. open questions; allowing participants to voice their priorities; comparing field notes to transcripts, multi-disciplinary teams who independently code and interpret and agreement on predominant themes based on discussion/negotiation. Overall, we have aimed to be transparent in our description of our methods to improve the robustness of our data driven claims.
| REVIEWER       | Dr Karim Raza                                      |
|               | Reader in Clinical Rheumatology and Honorary Consultant Rheumatologist |
|               | University of Birmingham, UK                       |
| REVIEW RETURNED | 04-Jan-2013                                       |

| THE STUDY           | Statistics not relevant for qualitative research |
| GENERAL COMMENTS    | The authors have addressed all my comments to my satisfaction. |