BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (http://bmjopen.bmj.com/site/about/resources/checklist.pdf) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

**ARTICLE DETAILS**

<table>
<thead>
<tr>
<th>TITLE (PROVISIONAL)</th>
<th>The outcome and cost effectiveness of nurse led care in the community in people with rheumatoid arthritis: a non-randomised pragmatic study.</th>
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</thead>
<tbody>
<tr>
<td>AUTHORS</td>
<td>Watts, Richard; Mooney, Janice; Barton, Garry; MacGregor, Alex; Shepstone, Lee; Irvine, Lisa; Scott, David</td>
</tr>
</tbody>
</table>

**VERSION 1 - REVIEW**

<table>
<thead>
<tr>
<th>REVIEWER</th>
<th>Mwidimi Ndosi</th>
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<tbody>
<tr>
<td></td>
<td>School of Healthcare, University of Leeds, Leeds, UK</td>
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<tr>
<td>REVIEW RETURNED</td>
<td>25-Mar-2015</td>
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</tbody>
</table>

**GENERAL COMMENTS**

The effective of nurse-led care in the community has not been evaluated before. This is therefore an important and timely study which will make an important contribution to the current knowledge on the innovative models of care for people with RA. Being a non-randomised study however limits the conclusions made by the authors and there is evident bias in the statements made in the results and discussion sections which are not supported by the results. Better (transparent) reporting especially in the methods section and the results (including the p-values) will help reduce the bias in the reporting and will improve the quality of the paper. My comments have addressed different sections of the paper to encourage more transparent reporting and interpretation of the results in the context of what we already know.

Title
The label of ‘pragmatic study’ in the title implies that this was a randomized controlled trial as the terms ‘pragmatic’ and ‘explanatory’ are used to describe different attitudes of RCT. A more accurate title would be: The outcome and cost effectiveness of nurse led care in the community in people with rheumatoid arthritis: a non-randomised controlled study OR The outcome and cost effectiveness of nurse led care in the community in people with rheumatoid arthritis: an observational study

Abstract
In the results section, why have you chosen to report the NHS perspective rather than healthcare perspective?

When reporting the differences please report the p-values alongside mean differences and the corresponding 95%CI.

The conclusion does not reflect the overall results of this study. I guess when the main aspects of the report have been amended, the results and the conclusion in the abstract will change.
Background
In the UK the titles: 'rheumatology nurse practitioner' and 'clinical nurse specialist' reflect the same role in the rheumatology services. Authors may want to clarify this especially for the benefit of the international audience.

Also, the authors may want to refer the clinics as 'nurse-led clinics in the community' instead of 'RP clinics' which can be confusing. The former would be consistent with literature.

In the references list, can you please provide more information for reference 2 i.e. the author name, publisher or website url. Also, I have gone through the archive in The Journal of Rheumatology in 2001, and I cannot find reference #6. Can you check if you have the correct reference please?

This study is about the outcome and cost-effectiveness of nurse-led care in the community. I would expect the introduction to briefly describe what is already known about the clinical and cost-effectiveness of nurse-led care in people with RA but this is not mentioned at all in the introduction. A quick PubMed search reveals over 10 RCTs of effectiveness of nurse-led care in RA, three of which have reported cost-effectiveness and 2 systematic reviews.

Pg4 Line 22-23. Authors claim that patients attending RP clinics report high levels of satisfaction. Reference 3 is an editorial and 6 does not appear in PubMed or in the J Rheumatol search. Could you support this statement by primary references (preferably from RCTs or systematic reviews)? Why have you chosen to mention satisfaction only while there are other outcomes of equal (if not more) importance such as physical function, disease activity, quality of life, pain, fatigue, stiffness, psychological well-being amongst others in the literature?

The justification of this study seems to be a response to the recent development of RP clinics in primary care in Norfolk. The authors then suggest that increased health benefits are achieved at an increased cost using references 8-10 which are older (between years 2000-2004) than the current developments. The research question and its economic importance are not mentioned anywhere in the introduction. Please add this information and state clearly what this research adds to what is already known in this field.

Methods
In this study, the outcomes (and costs) of independent PR clinics in primary care were compared with those of rheumatologist-led clinics in secondary care. Can you justify why you chose this comparator (rheumatologist-led clinics) instead of the equivalent service such as nurse-led clinics in the secondary care?

Please justify the choice of non-randomised design in this area.

Given this was a non-randomised study, I would expect a detailed explanation of patient allocation and whether there was any care taken or effort given to reduce selection bias. How did you try to ensure internal validity as much as it can be achieved in this non-randomised trial?

There is some information about the outreach clinic but only a
sentence about hospital clinics. Were there any known systematic differences between the two types of clinics being compared, which would impact on the validity of the findings? This validity of this study depends on clear description of both interventions being compared. Unless the authors adequately describe both interventions then we will have serious concerns about the internal validity of the study.

What was the sample size calculations based on? Please describe what were the ‘potential confounders’?

Page 7, line 5-6. The authors say: ‘However, since the costing of such care is sometimes considered controversial….’ Can you describe what exactly is meant by ‘controversial’?

The baseline characteristics reveal that 17 (9%) of the patients in the community were on biologic DMARDs compared to 3 (2%) in the hospital group (Table 1). This alone would have significant impact on the cost (Table 2). This appears to be the main known confounder and since this was not a random occurrence (as it would have been the case in an RCT), one would expect baseline use of biologics to be adjusted for in all your analyses rather than just carrying out a sensitivity test.

It would help the reader if in all your tables of results (Tables 2, 3, 4 and S2) you would insert the p-values and state the assumptions/hypotheses being tested in the table legends - whether testing no difference or against a non-inferiority margin.

Page 12 line 26. Authors say the regression results are shown in Supplementary Table 3, but going to that table I see data availability at each time point – please correct this.

To avoid misleading conclusions, please provide cost-effective plane and CEAC after adjusting for biologics use. This can be presented as figure 2a, b, c &d. Please provide figure legends to help reader understand what the quadrants mean. Also, in the CEAC graph, indicate the NICE WTP thresholds and state in the figure legends what this means.

Discussion
There is new information in the discussion section - that the two groups were reasonably well-matched at baseline in terms of disease severity. Can you please explain the methods section how you achieved this? How did you measure the disease severity? Did you have follow-up data for disease severity in addition to disability (HAQ) and EQ5D?

The authors overall conclusion of the study is that they found that care in the community was associated with higher mean cost and no clinically significant change in effectiveness. Is this conclusion valid after adjusting for the obvious confounder – the use of biologics?

Pg 15, lines 20-23: Authors say that the analysis excluding the patients receiving biologic DMARDs at baseline showed that community care was still associated with greater costs. Were these costs significant? This statement is not supported by the costs data as the health professional contact costs were higher in the hospital group (£642 vs £581). Also comparing the direct costs of the health professional visits in Supplementary Table S3.
In the imitations, the authors admit that they were unable to calculate disease activity scores, but at they mentioned earlier that patients were well matched in terms of their disease severity. Can you please clarify how you assessed the disease severity?

Conclusion
The authors conclude that community based nurse-led care was not cost effective and base this conclusion on the lack of direct consultant support and the inability of the nurse practitioners to prescribe or perform joint injections. The results of the cost data however do not support this conclusion (Table 2 and Supplementary Table S3). The mean NHS costs excluding medications were higher in the hospital group (£928 vs £900), of course not significantly different, but making the conclusion above false.

Please consider how your results compare with those reported in the following studies.


In reference 28 (Little & Rubin), please add City

REVIEWER
Martyn Lewis
Keele University,
UK

REVIEW RETURNED
09-Apr-2015

GENERAL COMMENTS
This is an important paper and makes good use of non-randomised data.

My main reservation is regarding the use of the complete-case analysis as the main evaluation. Data is usually not missing completely at random, and hence an MAR-based analysis is more appropriate, and the sensitivity MI analysis would be preferred. This may get over some of the issues I have over the stated denominator numbers. For example, Table 2 shows n=130 for the Community group, yet the flowchart in Figure 1 states n=122 at 12 months, which is not possible under CCA. To further argue the preference for the MI analysis, the flowchart shows that loss to follow up is different between groups. Also within this lies my concern regarding the
Overall difference in cost effectiveness results shown in Table 4, which do not seem to align well with the data presented in Table 2 that show little differences in disaggregated resource use and time off work (except for biologic DMARDs). Yet in Table 4 there are substantial differences in cost-effectiveness through inclusion of societal costs. The contrast in biologic-use concerns me especially as it is the key NHS cost-driver, though Table 4 seems to show that the exclusion of participants on this resource makes little difference to the cost-effectiveness (despite there being a large difference in Table 2) - I wonder whether this is due to the difference in participants analysed between the tables under CCA? Time off work seems to be little different between the two groups so it is difficult to comprehend the large difference that appears in Table 4. As this was a non-randomised design, perhaps the authors could have been a bit more inclusive of baseline characteristics in their model adjustment (e.g. duration of pain / socio-working profile). Please could the authors check the tables to ensure that all referencing is provided in the legends. Moreover, in Table 4, the reference group for the regression analysis should be clearly indicated.

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**VERSION 1 – AUTHOR RESPONSE**

Reviewer Name Mwidimi Ndosi
Institution and Country School of Healthcare, University of Leeds, Leeds, UK
Please state any competing interests or state ‘None declared’: None declare

Please leave your comments for the authors below

The effective of nurse-led care in the community has not been evaluated before. This is therefore an important and timely study which will make an important contribution to the current knowledge on the innovative models of care for people with RA. Being a non-randomised study however limits the conclusions made by the authors and there is evident bias in the statements made in the results and discussion sections which are not supported by the results. Better (transparent) reporting especially in the methods section and the results (including the p-values) will help reduce the bias in the reporting and will improve the quality of the paper. My comments have addressed different sections of the paper to encourage more transparent reporting and interpretation of the results in the context of what we already know.

Title
The label of ‘pragmatic study’ in the title implies that this was a randomized controlled trial as the terms ‘pragmatic’ and ‘explanatory’ are used to describe different attitudes of RCT. A more accurate title would be: The outcome and cost effectiveness of nurse led care in the community in people with rheumatoid arthritis: a non-randomised controlled study OR The outcome and cost effectiveness of nurse led care in the community in people with rheumatoid arthritis: an observational study
We have altered the title.

Abstract
In the results section, why have you chosen to report the NHS perspective rather than healthcare perspective?
To reflect the international readership we have renamed this healthcare (cost items/analysis unchanged)

When reporting the differences please report the p-values alongside mean differences and the corresponding 95%CI.
P values have been added abstract and tables.

The conclusion does not reflect the overall results of this study. I guess when the main aspects of the report have been amended, the results and the conclusion in the abstract will change. We have amended the abstract appropriately to reflect the key results.

Background
In the UK the titles: ‘rheumatology nurse practitioner’ and ‘clinical nurse specialist’ reflect the same role in the rheumatology services. Authors may want to clarify this especially for the benefit of the international audience. We have clarified this point

Also, the authors may want to refer the clinics as ‘nurse-led clinics in the community’ instead of ‘RP clinics’ which can be confusing. The former would be consistent with literature. The terminology has been adjusted as requested

In the references list, can you please provide more information for reference 2 i.e. the author name, publisher or website url. Also, I have gone through the archive in The Journal of Rheumatology in 2001, and I cannot find reference #6. Can you check if you have the correct reference please? Reference 2 (now 3) URL has been added
More readily accessible references have been substituted for reference 6. References 4-8

This study is about the outcome and cost-effectiveness of nurse-led care in the community. I would expect the introduction to briefly describe what is already known about the clinical and cost-effectiveness of nurse-led care in people with RA but this is not mentioned at all in the introduction. A quick PubMed search reveals over 10 RCTs of effectiveness of nurse-led care in RA, three of which have reported cost-effectiveness and 2 systematic reviews.
Thank you. We have revised the background to refer to these papers and referenced them.

Pg4 Line 22-23. Authors claim that patients attending RP clinics report high levels of satisfaction. Reference 3 is an editorial and 6 does not appear in PubMed or in the J Rheumatol search. Could you support this statement by primary references (preferably from RCTs or systematic reviews)? Why have you chosen to mention satisfaction only while there are other outcomes of equal (if not more) importance such as physical function, disease activity, quality of life, pain, fatigue, stiffness, psychological well-being amongst others in the literature?
We have revised the background to take account of this and provided supporting references

The justification of this study seems to be a response to the recent development of RP clinics in primary care in Norfolk. The authors then suggest that increased health benefits are achieved at an increased cost using references 8-10 which are older (between years 2000-2004) than the current developments. The research question and its economic importance are not mentioned anywhere in the introduction. Please add this information and state clearly what this research adds to what is already known in this field.

We have clarified the introduction relating to this point and provided a brief summary of costs of RA services. The relative costs of providing community based care versus hospital based care is unknown and led us to hypothesize that nurse-led care might be cheaper, but previous studies have shown that consultant-led community outreach services are more expensive. The research question was: are nurse-led community clinics for RA cost-effective compared to rheumatologist-led outpatient clinics for RA?
Methods

In this study, the outcomes (and costs) of independent PR clinics in primary care were compared with those of rheumatologist-led clinics in secondary care. Can you justify why you chose this comparator (rheumatologist-led clinics) instead of the equivalent service such as nurse-led clinics in the secondary care?

In our service setting secondary care services are provided by a mix of rheumatologist clinics and nurse led clinics. Patients attend both types of clinic in secondary care. We wished therefore to compare our secondary care services with services provided by community NLC. Please justify the choice of non-randomised design in this area.

We chose a observational non-randomised design as we did not wish to disrupt or alter the pattern of care.

Norfolk covers wide geographical spread – community care closer to home perceived as more convenient for patients living further away from the central hospital. The NLC arose from the desire to improve satisfaction for those in rural locations (less time/travel) however need to assess the costs and outcomes of such services compared to standard outpatient care.

Given this was a non-randomised study, I would expect a detailed explanation of patient allocation and whether there was any care taken or effort given to reduce selection bias. How did you try to ensure internal validity as much as it can be achieved in this non-randomised trial? By trying to recruit from all clinics we hope to reduce selection bias. We reviewed recruitment during the study to ensure balance between NLC and RLC.

There is some information about the outreach clinic but only a sentence about hospital clinics. Were there any known systematic differences between the two types of clinics being compared, which would impact on the validity of the findings? This validity of this study depends on clear description of both interventions being compared. Unless the authors adequately describe both interventions then we will have serious concerns about the internal validity of the study.

Further details have been provided regarding the structure of the hospital based services

What was the sample size calculations based on? Please describe what were the ‘potential confounders’? We adjusted for a confounding imbalance in HAQ at baseline.

Page 7, line 5-6. The authors say: ‘However, since the costing of such care is sometimes considered controversial….’ Can you describe what exactly is meant by ‘controversial’? These controversies are discussed in the cited publication. (Sach and Whynes, 2003) Several costing methodologies exist regarding how to value lost working days, and costs may change substantially based on each method. We have applied the human capital approach (using average rate of hourly earnings) however due to the lack of consensus in the field, NICE recommends that these costs are reported separately, as we have in this sensitivity analysis.

The baseline characteristics reveal that 17 (9%) of the patients in the community were on biologic DMARDs compared to 3 (2%) in the hospital group (Table 1). This alone would have significant impact on the cost (Table 2). This appears to be the main known confounder and since this was not a random occurrence (as it would have been the case in an RCT), one would expect baseline use of biologics to be adjusted for in all your analyses rather than just carrying out a sensitivity test.
All cost regressions adjusted for baseline costs, age and sex. Therefore the cost of biologics at baseline were taken into account.

It would help the reader if in all your tables of results (Tables 2, 3, 4 and S2), you would insert the p-values and state the assumptions/hypotheses being tested in the table legends - whether testing no difference or against a non-inferiority margin. We have added P values to all tables and added the hypothesis added to legend where appropriate.

Page 12 line 26. Authors say the regression results are shown in Supplementary Table 3, but going to that table I see data availability at each time point – please correct this. We apologise for this error, we have now incorporated the data availability data into the C/E results and add the regression results which had been missed when submitting the original manuscript.

To avoid misleading conclusions, please provide cost-effective plane and CEAC after adjusting for biologics use. This can be presented as figure 2a, b, c & d. Please provide figure legends to help reader understand what the quadrants mean. Also, in the CEAC graph, indicate the NICE WTP thresholds and state in the figure legends what this means.

Thank you. We have provided this data as figures 2a-d.

Discussion
There is new information in the discussion section - that the two groups were reasonably well-matched at baseline in terms of disease severity. Can you please explain the methods section how you achieved this?

The HAQ and EQ-5D scores at baseline were given in Table 1.

How did you measure the disease severity? Did you have follow-up data for disease severity in addition to disability (HAQ) and EQ5D?

HAQ and EQ-5D were performed at 0, 6 and 12 months and the results given in Table 3.

The authors overall conclusion of the study is that they found that care in the community was associated with higher mean cost and no clinically significant change in effectiveness. Is this conclusion valid after adjusting for the obvious confounder – the use of biologics?

We consider the conclusion to be valid as our results indicate the following:

- NHS costs adjusting for baseline – NLC non significantly higher
- NHS+social costs adjusting for baseline - NLC non significantly higher
- NHS costs excluding meds – NLC non significantly higher
- NHS costs excluding ppt on biologics at baseline - NLC non significantly higher

Pg 15, lines 20-23: Authors say that the analysis excluding the patients receiving biologic DMARDs at baseline showed that community care was still associated with greater costs. Were these costs significant? This statement is not supported by the costs data as the health professional contact costs were higher in the hospital group (£642 vs £581). Also comparing the direct costs of the health professional visits in Supplementary Table S3.

Community costs are still higher because even when excluding patients receiving biologic DMARDs at baseline, during the course of the year follow-up more patients in community arm started biologics than in the hospital arm. Biologics are such a high cost driver that this creates disparity even though health prof visits / admissions etc. were relatively similar between arms. P values now added to table 4 show that community care was still associated with greater costs, but again this was non-significant (p=0.376).

In the limitations, the authors admit that that they were unable to calculate disease activity scores, but
at they mentioned earlier that patients were well matched in terms of their disease severity. Can you please clarify how you assessed the disease severity?

We assessed disease severity using HAQ and EQ-5D. As mentioned in the text we did not access activity.

Conclusion

The authors conclude that community based nurse-led care was not cost effective and base this conclusion on the lack of direct consultant support and the inability of the nurse practitioners to prescribe or perform joint injections. The results of the cost data however do not support this conclusion (Table 2 and Supplementary Table S3).

Supplementary table 2 suggests that visits to the rheumatologist were more frequent in the community group suggesting that rather than discussion between nurse and rheumatologist during a secondary care visit in the community group patients were referred for a formal appointment.

Joint injections offered to patients in community arm but they had to travel to main hospital to obtain these. Actually referred to Rheumatologist more often in community arm than in standard outpatient.

The mean NHS costs excluding medications were higher in the hospital group (£928 vs £900), of course not significantly different, but making the conclusion above false.

We have changed the final conclusion paragraph to reflect this and to bring into line with the abstract.

Please consider how your results compare with those reported in the following studies. We have discussed these in the background and in the discussion


In reference 28 (Little & Rubin), please add City

We have done this

Reviewer Name Martyn Lewis
Institution and Country Keele University, UK
Please state any competing interests or state 'None declared': None

Please leave your comments for the authors below
This is an important paper and makes good use of non-randomised data.

My main reservation is regarding the use of the complete-case analysis as the main evaluation. Data
is usually not missing completely at random, and hence an MAR-based analysis is more appropriate, and the sensitivity MI analysis would be preferred. We have repeated all analyses using the MI dataset and provided the cost-effective plane and CEAC as supplementary figures.

This may get over some of the issues I have over the stated denominator numbers. For example, Table 2 shows n=130 for the Community group, yet the flowchart in Figure 1 states n=122 at 12 months, which is not possible under CCA. We have clarified how the numbers in Figure 1 were calculated and redrawn the flow chart.

To further argue the preference for the MI analysis, the flowchart shows that loss to follow up is different between groups. Also within this lies my concern regarding the overall difference in cost effectiveness results shown in Table 4, which do not seem to align well with the data presented in Table 2 that show little differences in disaggregated resource use and time off work (except for biologic DMARDs). Yet in Table 4 there are substantial differences in cost-effectiveness through inclusion of societal costs. The contrast in biologic-use concerns me especially as it is the key NHS cost-driver, though Table 4 seems to show that the exclusion of participants on this resource makes little difference to the cost-effectiveness (despite there being a large difference in Table 2)) - I wonder whether this is due to the difference in participants analysed between the tables under CCA? Time off work seems to be little different between the two groups so it is difficult to comprehend the large difference that appears in Table 4. As this was a non-randomised design, perhaps the authors could have been a bit more inclusive of baseline characteristics in their model adjustment (e.g. duration of pain / socio-working profile).

We have adjusted the model for baseline costs, baseline outcome measures (QALY or HAQ), age and sex and provided a revised table 4.

The cost-effective plane and CEAC for the multiple imputed data set is provided in supplementary figure.

Please could the authors check the tables to ensure that all referencing is provided in the legends. Thank you. We have corrected this.

Moreover, in Table 4, the reference group for the regression analysis should be clearly indicated. We have clarified the column headings.

<table>
<thead>
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<th>REVIEWER</th>
<th>Mwidimi Ndosi</th>
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<tbody>
<tr>
<td>University of Leeds</td>
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</table>

| REVIEW RETURNED | 14-May-2015 |

| GENERAL COMMENTS | Overall comments
Several issues have been addressed in the revised manuscripts although the reporting of some results and the conclusion will need revision to avoid misleading. There is a tendency to make non-significant findings sound as real differences even when they are not clinically significant.

For example, the authors report: ‘We found that the community NLC group had a higher level of functional disability according to the HAQ…’ then later say: ‘though the differences … were not clinically significant.’

And elsewhere: ‘The results suggest that community care may be associated with non-significant higher costs with no significant...’ |

VERSION 2 – REVIEW
Isn't the whole point of undertaking inferential analyses to ascertain if there is enough evidence to reject the null hypothesis? If the authors are happy to say there is no (significant) difference in clinical outcomes, why is it difficult to also say that there is no (significant) difference in the cost?

If the difference is non-significant, we are unable to reject the null hypothesis. However, we cannot conclude that the null hypothesis is true either.

If the community NLC clinical outcomes were significantly worse than the intervention and the cost was same (or significantly higher), then we would reject the intervention.

However based on the results of this study, (if I have understood the results well) the intervention outcomes are not (significantly) different from those of the control and the cost of the intervention is also not (statistically) different from the control. In other words, there is neutral cost and effect. It is therefore not accurate to say that the intervention was more costly – there is no evidence for this. The implication here may be to ask the question: is there any other reason to accept/reject the intervention? Please see figure 1 in Nixon et al (2001) BMJ, 322(7302), 1596-1598.

Abstract
Consider amending the sentence: ‘… community NLC group had a higher level of functional disability …though the differences … were not clinically significant.’ Also reword the conclusion accordingly.

Background
Minor/discretionary suggestions: Authors have now clarified the RP clinics (community-based nurse-led clinics) but in different places in the manuscripts there are references to ‘nurse-led clinics in the community’ and ‘nurse-led clinics’ (implying in the hospital nurse-led clinics) and in other places ‘RP-clinics in the community’. It would help the (international) readers if once the terms are defined, they are used consistently throughout the report e.g. community-based nurse-led clinic used throughout to differentiate from hospital-based nurse-led clinics.

Results

Table 4
Correct typos in the table legends: ‘…against no difference berwqeen groups.’

Discussion
Pg 18 line 21-24 ‘… analysis excluding the patients receiving biologic DMARDs at baseline showed that community care was still associated with greater costs.’ Was this significant? If not please amend.

Conclusion
Again, if the interpretation of the (non-significant) results is no enough evidence, the conclusion should reflect this.
REVIEWER
Martyn Lewis
Keele University, UK

REVIEW RETURNED
21-May-2015

GENERAL COMMENTS
Thank you for addressing my previous concerns. I am happy with the updates provided.

I have one remaining concern, which relates to the conclusion of the paper (and abstract). You state "... conclude that community NLC may be associated with non-significant higher costs with no significant differences in clinical outcomes when compared with RLC in secondary care". I agree that in statistical terms the observed differences were non-significant, but I do not like the phrase may be associated with non-significant higher cost. My reflection is that the study found community NLC to be inferior in terms of higher cost and worse outcome which translated to a low probability of being cost effective compared to RLC in secondary care, although differences were not statistically significant. The authors may wish to review this.

VERSION 2 – AUTHOR RESPONSE

Reviewer Name Mwidimi Ndosi
Institution and Country University of Leeds

Please state any competing interests or state ‘None declared’: None

Please leave your comments for the authors below

Overall comments
Several issues have been addressed in the revised manuscripts although the reporting of some results and the conclusion will need revision to avoid misleading. There is a tendency to make non-significant findings sound as real differences even when they are not clinically significant.

For example, the authors report: ‘We found that the community NLC group had a higher level of functional disability according to the HAQ…’ then later say: ‘though the differences … were not clinically significant.’

And elsewhere: ‘The results suggest that community care may be associated with non-significant higher costs with no significant differences in clinical outcomes.’

Isn’t the whole point of undertaking inferential analyses to ascertain if there is enough evidence to reject the null hypothesis? If the authors are happy to say there is no (significant) difference in clinical outcomes, why is it difficult to also say that there is no (significant) difference in the cost?

If the difference is non-significant, we are unable to reject the null hypothesis. However, we cannot conclude that the null hypothesis is true either.

If the community NLC clinical outcomes were significantly worse than the intervention and the cost was same (or significantly higher), then we would reject the intervention.

However based on the results of this study, (if I have understood the results well) the intervention outcomes are not (significantly) different from those of the control and the cost of the intervention is also not (statistically) different from the control. In other words, there is neutral cost and effect. It is
therefore not accurate to say that the intervention was more costly – there is no evidence for this. The implication here may be to ask the question: is there any other reason to accept/reject the intervention? Please see figure 1 in Nixon et al (2001) BMJ, 322(7302), 1596-1598.

Thank you for these comments. We have revised the manuscript we hope in line with these points, in particular in the specific points mentioned below.

Abstract
Consider amending the sentence: ‘… community NLC group had a higher level of functional disability …though the differences … were not clinically significant.’ Also reword the conclusion accordingly.

We have amended also to take into account the comments of the second reviewer.

Background
Minor/discretional suggestions: Authors have now clarified the RP clinics (community-based nurse-led clinics) but in different places in the manuscripts there are references to ‘nurse-led clinics in the community’ and ‘nurse-led clinics’ (implying in the hospital nurse-led clinics) and in other places ‘RP-clinics in the community’. It would help the (international) readers if once the terms are defined, they are used consistently throughout the report e.g. community-based nurse-led clinic used throughout to differentiate from hospital-based nurse-led clinics.

We have made the terminology more consistent throughout the manuscript

Results

Table 4
Correct typos in the table legends: ‘…against no difference berwqeen groups.’

Thank you we have corrected this.

Supplementary Fig 1a
What do the green and purple line represent?

We have corrected this, removed the coloured lines and provided a revised figure

Discussion
Pg 18 line 21-24 ‘… analysis excluding the patients receiving biologic DMARDs at baseline showed that community care was still associated with greater costs.’ Was this significant? If not please amend.

We have amended this

Conclusion
Again, if the interpretation of the (non-significant) results is no enough evidence, the conclusion should reflect this.

We have amended this also to include the view of the second reviewer.

Reviewer Name Martyn Lewis
Institution and Country Keele University, UK
Please state any competing interests or state 'None declared': None declared
Please leave your comments for the authors below
Thank you for addressing my previous concerns. I am happy with the updates provided.

I have one remaining concern, which relates to the conclusion of the paper (and abstract). You state ".. conclude that community NLC may be associated with non-significant higher costs with no significant differences in clinical outcomes when compared with RLC in secondary care". I agree that in statistical terms the observed differences were non-significant, but I do not like the phrase may be associated with non-significant higher cost. My reflection is that the study found community NLC to be inferior in terms of higher cost and worse outcome which translated to a low probability of being cost effective compared to RLC in secondary care, although differences were not statistically significant. The authors may wish to review this.

Thank you. We have revised the abstract to reflect your comment.
The outcome and cost-effectiveness of nurse-led care in the community for people with rheumatoid arthritis: a non-randomised pragmatic study

Richard A Watts, Janice Mooney, Garry Barton, Alex J MacGregor, Lee Shepstone, Lisa Irvine and David G I Scott


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