HEALTH PSYCHOLOGY BULLETIN

EDITORIAL HISTORY

More Harm than Good? A Pilot of a Motivational Interviewing Based Intervention for Increasing Readiness to Improve Nutrition in Young People Experiencing a First Episode of Psychosis

Fulton, E., Peet, M., & Williamson, K.

This document contains the editorial history, organized into three sections. This first section, section 0, provides background information about the paper and the review procedure. Section 1 is organized chronologically and contains the editorial communication and peer review history. Section 2 contains the successive preprints and is organized anti-chronologically.

DOI of article:	10.5334/hpb.10
DOI of this editorial history:	10.5334/hpb.10.pr1
Article submitted:	2017-10-12
Revision submitted:	2018-03-06
Article accepted:	2018-07-11
Executive editor:	Gudrun Sproesser
Senior editor:	Robbert Sanderman
Peer reviewer A:	Emma Davies
Peer reviewer B:	Johanna Nurmi

Cite this document as:

Fulton, E., Peet, M., & Williamson, K. (authors); Davies, E., & Nurmi, J. (reviewers); Sproesser, G., & Sanderman, R. (editors) (2019) Editorial history for 'More Harm than Good? A Pilot of a Motivational Interviewing Based Intervention for Increasing Readiness to Improve Nutrition in Young People Experiencing a First Episode of Psychosis'. *Health Psychology Bulletin*, 3(1).
DOI: <http://doi.org/10.5334/hpb.10.pr1>

Paper abstract

The relationship between nutrition and mental health, as well as physical health, is well known. Mental Health Services in the UK and worldwide are recognising the need for nutritional care, however eliciting a change in eating habits in patients/service users is a challenge. The effects of a 'Psych-Nutritional Intervention' (PNI) using Motivational Interviewing ($n = 30$) was compared with a 'Treatment as Usual' (TAU) involving standard nutritional advice ($n = 21$) and a control group (no nutritional support) ($n = 22$). The sample consisted of young people aged 18–35 years old with a diagnosis of psychosis, who were currently under the care of a UK specialist National Health Service (NHS) Mental Health team (Early Intervention for Psychosis Team). Nutritional knowledge was assessed at baseline across the groups. Readiness to Change eating habits was measured at baseline and a further two time points post intervention. Although there were no significant between group differences, the PNI group elicited both the most progression in terms of readiness to change eating habits, but also the most regression. The use of MI may be anti-therapeutic for those who are not ready to consider make changes to their eating habits, and this requires further investigation. Greater emphasis on the importance of assessing and selecting who is most likely to benefit from interventions is necessary.

Background

This peer review history is published under Health Psychology Bulletin's peer review policy. Peer review at Health Psychology Bulletin (HPB) is blind, but upon acceptance of an article, the entire peer review history is made public. This policy has two aims. First, it makes the reviews citable, rewarding reviewers for their reviews, incentivizing thorough, thoughtful reviews, and stimulating constructive, considerate reviews and responses. Second, to yield the best of both worlds in terms of design of the review procedure. The common procedure of shielding authors' and peer reviewers' identities aims to prevent undue harshness or leniency. However, this anonymity also protects reviewers who make unreasonable requests or statements that are inconsistent with the literature, and authors who refuse to respond adequately to reviewers' requests. These risks are ameliorated by unblinding and publishing the peer review procedure upon paper acceptance.

Health Psychology Bulletin

Health Psychology Bulletin (HPB) is an official journal of the European Health Psychology Society (EHPS). It implements a number of innovative practices such as this peer review procedure, a strong full disclosure policy, a two-tiered review procedure, and explicitly welcoming null findings, replications, and reports of lessons learned such as failed manipulations or measurement instruments, as well as regular articles.

Section 1: editorial correspondence

This section is comprised of the editor–author correspondence followed by the review reports in chronological order.

Dear Dr Peters,

Please accept the attached manuscript for consideration in your journal 'Health Psychology Bulletin'. You may recall that we communicated over email in the summer to query the possible suitability of the article for HPB, in light of the null findings and lack of SPSS data file for the analysis package. I look forward to your thoughts on what was my thesis research before I joined Coventry University, conducted some time ago. The paper describes a pilot part randomised controlled trial of an intervention to improve eating habits using motivational interviewing for young people with psychosis. There were a number of methodological flaws that I hope have been clearly discussed in the limitations. The 'Replication' and 'Analysis' Packages can be found via the OSF link as instructed:

https://osf.io/p6z8r/?view_only=50081ee6c422455bbbe52a8cadcl8bac

The reasons for the omission of the data file is outlined within this, in a separate file as requested. The intervention documents and other research files are listed in the replication package with explanations of the unavailable letters.

Please do not hesitate to get in touch if you have any queries, and I very much look forward to hearing from you. I hope the article may be suitable for your journal, as obviously it has never been published elsewhere, which has always been a regret.

Yours Sincerely,

Dr Emmie Fulton

Health Psychologist/Research Fellow in eHealth

Coventry University & Public Health Warwickshire, UK.

Editor/Author Correspondence

Section Editor
2018-01-05 02:30 PM

Subject: [HPB] Editor Decision – “More harm than good? A pilot of a Motivational Interviewing based intervention for increasing readiness to improve nutrition in young people experiencing a first episode of psychosis.”

Dear Dr emmie fulton,

After review, we have reached a decision regarding your submission to Health Psychology Bulletin, "More harm than good? A pilot of a Motivational Interviewing based intervention for increasing readiness to improve nutrition in young people experiencing a first episode of psychosis.". Our decision is to request revisions of the manuscript. These revisions may then undergo further peer review prior to acceptance.

The full review information is included at the bottom of this email. There may also be a copy of the manuscript file with reviewer comments available once you have accessed the submission account. Please revise the manuscript according to the reviewers' comments. Especially, as stated by both reviewers, please decide whether the study is a test of feasibility or of intervention efficacy and revise the manuscript accordingly.

Also, in line with suggestions from Reviewer C, please explain in the introduction section how the used MI intervention is comparable or different to previously used MI interventions.

Moreover, as stated by Reviewer I, please provide information how the TAU treatment looked like in the methods section (which was also required by Reviewer C) and include references to previous research in the discussion section.

In addition to the reviewers' comments please consider the following points:

- Although it is a pilot study, please include full statistical results throughout the manuscript (e.g., F, df, p, effect size), also for non-significant results (e.g., p. 10, 11). Please also provide full details of the 3x3 ANOVA, including means and SDs for T1-T3 (potentially in Table 4), statistical results of main effects and the interaction.
- Please consider common strategies to treat missing data.
- Please include BMI instead of weight and height throughout the manuscript. If it is not possible to get access to BMI data, please display this already in the methods section.
- Please include information on the possible range of readiness to change (p. 7/8).
- P. 11: "although the means revealed a greater increase in the Control group (see Table. 5)". The greatest change occurred in the TAU group, not in the control group, right?
- Please provide more information about Figure 1: what is displayed on the y-axis? Number of people or means?
- The wide range of change between T1 and T2 is indeed very interesting. Do authors have any ideas what might be potential moderator variables here?

To access your submission account, follow the below instructions:

- 1) login to the journal webpage with username and password
- 2) click on the submission title
- 3) click 'Review' menu option
- 4) download Reviewed file and make revisions based on review feedback
- 5) upload the edited file
- 6) Click the 'notify editor' icon and email the confirmation of re-submission and any relevant comments to the journal.

Please ensure that your revised files adhere to our author guidelines, and that the files are fully copyedited/proofed prior to upload. Please also ensure that all copyright permissions have been attained. This is the last opportunity for major editing, therefore please fully check your file prior to re-submission.

If you have any questions or difficulties during this process, please do contact us.

Please could you have the revisions submitted by January 19th. If you cannot make this deadline, please let us know as early as possible.

Kind regards,

Dr Gudrun Sproesser
University of Konstanz
gudrun.sproesser@uni-konstanz.de

Reviewer C:

More harm than good? A pilot of a Motivational Interviewing based intervention for increasing readiness to improve nutrition in young people experiencing a first episode of psychosis

Thank you for the opportunity to review this paper, which at the outset highlights a very clear challenge that is faced when developing interventions to target healthy eating young people with mental health problems.

The paper begins by outlining the problem of weight gain in the target population very clearly and then goes on to suggest why informational interventions may not be effective. This is well justified.

The paper then goes on to introduce MI as a strategy for improving nutrition and reducing weight gain. However, the authors then highlight that a review together with a study by Niv et al 2014 found no significant impacts. For this reason, there needs to be a much clearer justification as to why MI has been chosen as an intervention strategy for the current study. The sentence in the first paragraph on the last page of the introduction is not sufficient given the studies showing no effect that have been discussed.

The section describing the format of MI could be moved – perhaps this could come before the section on previous studies and then the justification could follow.

What is also missing is something about how exactly the intervention content was developed and why. There is a brief mention of discussions with service users – were they involved in the development of the intervention and what feedback did they provide? What are the specific behaviour change techniques (BCTs) included? It appears that some form of goal setting was incorporated – but this is unclear.

The methods section would benefit from restructuring in line with standardised reporting of intervention trials. EG Using <http://www.consort-statement.org/> I realise this is a pilot but to allow replication and a clearer sense of the content of the interventions this would improve the methods section.

At present it would be difficult to replicate the PNI intervention from the paper and so further detail about the content is needed. The reader also needs to know more about what constitutes TAU in this group.

There is a good level of detail about how participants were included and excluded in the study. Given that there are likely to be significant challenges when recruiting this patient group, the study team have done well to recruit the numbers involved at the start. It is a shame that many were lost at T2 and 3.

Results – given that this is a pilot study we would not usually expect to see significance testing.

Overall there are some important lessons to be learned from the study. However it might be more appropriate to write this study up with more focus on the pilot/ feasibility of the intervention, for many of the reasons raised. Given the tentative nature of the findings, I would suggest that the 'more harm than good' part of the title is revised. Further qualitative exploration with service users could enlighten us about whether the findings would represent real harms.

Reviewer I:

Thank you for conducting this important study in a vulnerable and challenging target population. It raises relevant questions on the types of interventions to deliver on patients with severe mental disorders.

To increase the readability of the paper, it needs to be made very clear through the paper whether the study is about those suffering First Episode Psychosis (as the title suggests) or those suffering from psychotic disorders in general. It is somewhat confusing that the title and methods refer to participants suffering from the First Episode Psychosis, but the introduction describes patients with schizophrenia and the study aims state "young people with psychosis" and not "young people with first episode psychosis".

Introduction:

'Readiness to change' needs to be defined and explained in the introduction. Currently it only appears in the aims section, and it is unclear to the reader what the construct refers to and whether it encompasses also eating behaviour or only psychological readiness.

An important factor for understanding the patient responses is to know more about the intervention that they received. I would ask the authors to add detailed information on who delivered the motivational interviewing, how much experience this person/these persons had using the method, how were they trained, had they used it is

similar settings before, did they know the participants beforehand. Also, all information about the intervention content should be added, i.e. which MI elements were used and were there any records of the intervention fidelity, i.e. checklists of MI elements used in each session. Who phoned that participants after two weeks and was it the same person than before? Did the participants know the nutritionist that visited them and was it the same person that first visited or called them?

Were the participants asked to fill in food diaries during the intervention? What does it mean that “In the setting of this study, the nutritionist’s goal has been to assess current dietary practice using food diaries”? This is not mentioned in the methods section.

There should be a reference for “[MI] Interventions may consist of one brief meeting (5-10 minutes) or a formal session (1- 2 hours)”.

The authors need to decide whether they use ‘Psych-Nutritional Intervention’ (abstract, methods section) or ‘Psycho-Nutritional Intervention’ (discussion) and always use the full words instead of acronyms. If they want to shorten the text, I would suggest calling the intervention group “intervention group” (or “motivational interviewing group”, instead of PNI) and the standard care “standard care” (instead of TAU).

Study aims need to be defined more clearly. In the current version, the aim is to “assess the feasibility” of MI intervention. However, the study does not assess intervention delivery or its acceptance. The conclusions do not mention feasibility but state that the study evaluated intervention efficacy. The actual research questions should be added clearly to both the abstract and the paper. Once the aims and research questions are clear, it is easier to assess whether the analyses are appropriate to answer those questions (as requested in <https://www.healthpsychologybulletin.com/about/editorialpolicies/>).

Methods:

The readers do not necessarily know what Early Intervention for Psychosis teams are and a better description would be necessary. e.g: Do these teams exist outside the intervention? Do all the participants attend these teams also outside the intervention? How did these teams become part of the intervention, how were they recruited? What is the relationship of authors to these teams? Please do not use abbreviations.

Please write ‘Kolmogorov–Smirnov test’ instead of ‘K-S test’.

Who assessed whether service users lacked mental capacity to participate and how?

I find this phrase unclear: “Weight was not compared across time points as healthy eating, rather than weight loss was the goal of the intervention.”

Results:

What were the exact research questions to be answered here?

Please change the statistics to follow APA format (spaces between, italics, etc)

Who assessed that “knowledge about nutrition was relatively good”. Was that a nutritionist? How was the conclusion made?

What were the post-hoc analyses mentioned at the end of the result section?

Please write ‘table 5.’ Instead of ‘table. 5’.

Discussion:

At the beginning of the discussion, instead of referring to “the Psycho-Nutritional Intervention”, I suggest to briefly specify the intervention content. Then, the results need to be summarised and described before proceeding to discussion of possible explanations.

“and missing data evident for baseline nutritional knowledge scores” – please clarify

The conclusions about MI effects need to be formulated more carefully. First of all, it needs to be clearly pointed out that the MI intervention was only one-time session. Secondly, authors could discuss the characteristics of this intervention population and if it is MI specifically that is not be suitable for patients with (first episode) psychosis (e.g., MI’s focus on ambivalence might not suit patients that are in a confused mindset). This should, however, include the limitations that first psychosis may set to intervention delivery. I suggest discussing the nature of first psychotic episode, which may be a very confusing time in a person’s life and thus not the optimal timing for an intervention. The results should not be generalised to all psychotic populations in which the symptoms and medication may more stable. Would there be previous studies showing that different types of psychotic disorders may react differently to treatment and that those with e.g. paranoia-type symptoms being potentially less likely to trust the intervention deliverer? Currently the discussion does not have one single reference and would need to base the conclusions on previous research.

Thirdly and most importantly, it needs to be discussed if something in the MI delivery might have affected the results and for this, a more detailed description of the intervention is needed in the methods section.

It would be also good to discuss also the limitations of the stage of change measure, e.g. collapsing heterogeneous concepts into one value. It is very different to increase intention compared to translating intention into behaviour. If the study data is still available, it would be useful to see to which extent participant move from intention phases to action phase, this would also decrease the worries about social desirability.

Due to the study limitations, it is a too strong argument that “The use of MI may be anti-therapeutic for those who are not ready to consider make changes to their eating habits”. If the authors want to state that MI might not be an

optimal approach, they need identify the specific participant group of this study and possible limitations in the delivery.

In general, it would be easier to comment the study if it had row numbers.

Despite this long list of wishes to improve the clarity of the study, I want to thank the authors for conducting a demanding and important intervention and for bringing the results into scientific debate.

Health Psychology Bulletin

<http://healthpsychologybulletin.com>

Author

2018-03-06 11:25 AM

Subject: More harm than good? A pilot of a Motivational Interviewing based intervention for increasing readiness to improve nutrition in young people experiencing a first episode of psychosis.

Dear Dr Sproesser and Dr Sanderman,

Please find attached a revised manuscript, title page (please note this how how been revised from the above) and abstract, having made extensive revisions based on all the reviewer suggestions. I very much hope that these amendments meet with your approval and I look forward to hearing from you. The only reviewer comment I was not able to uphold is the request to use the CONSORT statement for the methods, as I understood I was required to follow your journal layout. Please let me know if you wish me to revise this. I have also still used abbreviations on second mention due to the word count, but again please let me know if this needs to be amended also.

I am extremely grateful to you for considering this article, and very much hope you will welcome the improvements you, and your reviewers kindly suggested. I have learned a great deal from these insights and it has hugely helped in improving the paper. Thank you.

Best wishes,

Emmie Fulton

Health Psychology Bulletin

<http://healthpsychologybulletin.com>

Section Editor

2018-04-25 03:57 PM

Subject: [HPB] Editor Decision - "More harm than good? A pilot of a Motivational Interviewing based intervention for increasing readiness to improve nutrition in young people experiencing a first episode of psychosis."

Dear Dr emmie fulton,

After review, we have reached a decision regarding your submission to Health Psychology Bulletin, "More harm than good? A pilot of a Motivational Interviewing based intervention for increasing readiness to improve nutrition in young people experiencing a first episode of psychosis.". Our decision is to request revisions of the manuscript prior to acceptance for publication.

A summary of the requested edits from the editorial team can be found below. Please consider these points and revise the file accordingly:

The manuscript has substantially improved through the revision. However, there are still some points that need to be improved before publication is possible:

Major revisions:

- If I understand correctly, Figure 1 shows the min and max of the change score T2-T1 across the 3 groups. Hence, this represents only the values of 6 participants. I'm a bit worried to base results/conclusions on this reduced sample, especially as SDs do not support a greater variation in the intervention group than in the usual care group (table 5). So I recommend to include a graph displaying change scores of all participants, e.g., a histogram for each of the 3 groups.
- I am confused about the absolute level of readiness to change. Table 4 shows values around 10. However, in the methods section authors state that values can range from 20 to 100???
- The discussion section still misses to relate results and discussion points to previous research (e.g., there are no citations on p. 14). Please include this in the revision.

Minor revisions:

- Please go carefully through the manuscript and correct any typos/ check the grammar. Some sentences appear to include additional words and points in the middle of a sentence.
- Last line on p. 12: this should be "... greater increase in the Usual Care Group from T1 to T2" (rather than Tables 5 and 6), right?
- Authors might want to consider moving the information on p. 11 to the methods section.

- Please keep reporting of statistics in a consistent way (e.g., F and p values should be italicized).

Please submit a response letter together with your revision, describing how you incorporated the requested changes. Also, please use the track changes option in word to highlight the changes in your revision or, alternatively, use red font.

To access your submission account, follow the below instructions:

- 1) login to the journal webpage with username and password
- 2) click on the submission title
- 3) click 'Review' menu option
- 4) download Reviewed file and make revisions based on review feedback
- 5) upload the edited file
- 6) Click the 'notify editor' icon and email the confirmation of re-submission and any relevant comments to the journal.

Please ensure that your revised files adhere to our author guidelines, and that the files are fully copyedited/proofed prior to upload. Please also ensure that all copyright permissions have been attained. This is the last opportunity for major editing, therefore please fully check your file prior to re-submission.

If you have any questions or difficulties during this process, please do contact us.

Please could you have the revisions submitted by May, 25th. If you cannot make this deadline, please let us know as early as possible.

Kind regards,

Dr Gudrun Sproesser
University of Konstanz
gudrun.sproesser@uni-konstanz.de

Health Psychology Bulletin
<http://healthpsychologybulletin.com>

Author
2018-05-24 02:37 PM

Subject: More harm than good? A pilot of a Motivational Interviewing based intervention for increasing readiness to improve nutrition in young people experiencing a first episode of psychosis.

Dear Dr Spoesser,

Please find attached a second revised manuscript as requested, with reviewer comments and author responses (also attached as a supplementary file under the 'summary' section), for your review.

I very much look forward to hearing from you.

Best wishes,

Dr Emmie Fulton

Health Psychology Bulletin
<http://healthpsychologybulletin.com>

Section Editor
2018-07-11 10:30 AM

Subject: [HPB] Editor Decision - "More harm than good? A pilot of a Motivational Interviewing based intervention for increasing readiness to improve nutrition in young people experiencing a first episode of psychosis."

Dear Dr emmie fulton,

After review, we have reached a decision regarding your submission to Health Psychology Bulletin, "More harm than good? A pilot of a Motivational Interviewing based intervention for increasing readiness to improve nutrition in young people experiencing a first episode of psychosis.", and are happy to accept your submission for publication, pending the completion of copyediting and formatting processes.

As there are no further reviewer revisions to make, you do not have to complete any tasks at this point. The accepted submission will now undergo final copyediting. You will be contacted once this is complete to answer any queries that may have arisen during copyediting and to allow a final chance to edit the files prior to typesetting. If you wish to view your submission during this time, you can log in via the journal website.

The review information should be included in this email.

Kind regards,

Dr Gudrun Sproesser
University of Konstanz
gudrun.sproesser@uni-konstanz.de

Health Psychology Bulletin
<http://healthpsychologybulletin.com>

Subject

More Harm than Good? A Pilot of a Motivational Interviewing

Add Comment

* Denotes required field

Review

Reviewer A
2017-11-28 04:29 PM

For author and editor

Subject: More harm than good? A pilot of a Motivational Interviewing based intervention for increasing readiness to improve nutrition in young people experiencing a first episode of psychosis.

More harm than good? A pilot of a Motivational Interviewing based intervention for increasing readiness to improve nutrition in young people experiencing a first episode of psychosis

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The paper begins by outlining the problem of weight gain in the target population very clearly and then goes on to suggest why informational interventions may not be effective. This is well justified.

The paper then goes on to introduce MI as a strategy for improving nutrition and reducing weight gain. However, the authors then highlight that a review together with a study by Niv et al 2014 found no significant impacts. For this reason, there needs to be a much clearer justification as to why MI has been chosen as an intervention strategy for the current study. The sentence in the first paragraph on the last page of the introduction is not sufficient given the studies showing no effect that have been discussed.

The section describing the format of MI could be moved – perhaps this could come before the section on previous studies and then the justification could follow.

What is also missing is something about how exactly the intervention content was developed and why. There is a brief mention of discussions with service users – were they involved in the development of the intervention and what feedback did they provide? What are the specific behaviour change techniques (BCTs) included? It appears that some form of goal setting was incorporated – but this is unclear.

The methods section would benefit from restructuring in line with standardised reporting of intervention trials. EG Using <http://www.consort-statement.org/> I realise this is a pilot but to allow replication and a clearer sense of the content of the interventions this would improve the methods section.

At present it would be difficult to replicate the PNI intervention from the paper and so further detail about the content is needed. The reader also needs to know more about what constitutes TAU in this group.

There is a good level of detail about how participants were included and excluded in the study. Given that there are likely to be significant challenges when recruiting this patient group, the study team have done well to recruit the numbers involved at the start. It is a shame that many were lost at T2 and 3.

Results – given that this is a pilot study we would not usually expect to see significance testing.

Overall there are some important lessons to be learned from the study. However it might be more appropriate to write this study up with more focus on the pilot/ feasibility of the intervention, for many of the reasons raised. Given the tentative nature of the findings, I would suggest that the 'more harm than good' part of the title is revised. Further qualitative exploration with service

users could enlighten us about whether the findings would represent real harms.

Close

Review

Reviewer A
2017-12-21 11:20 PM

For editor

Subject: More harm than good? A pilot of a Motivational Interviewing based intervention for increasing readiness to improve nutrition in young people experiencing a first episode of psychosis.

Dear editor,

I was not sure if I should be directly pasting the review in the box that says "for author and editor" so I only paste it here. Please let me know if you will forward the text to the authors or if I should add it through the system. Thank you.

Thank you for conducting this important study in a vulnerable and challenging target population. It raises relevant questions on the types of interventions to deliver on patients with severe mental disorders.

To increase the readability of the paper, it needs to be made very clear through the paper whether the study is about those suffering First Episode Psychosis (as the title suggests) or those suffering from psychotic disorders in general. It is somewhat confusing that the title and methods refer to participants suffering from the First Episode Psychosis, but the introduction describes patients with schizophrenia and the study aims state "young people with psychosis" and not "young people with first episode psychosis".

Introduction:

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An important factor for understanding the patient responses is to know more about the intervention that they received. I would ask the authors to add detailed information on who delivered the motivational interviewing, how much experience this person/these persons had using the method, how were they trained, had they used it in similar settings before, did they know the participants beforehand. Also, all information about the intervention content should be added, i.e. which MI elements were used and were there any records of the intervention fidelity, i.e. checklists of MI elements used in each session. Who phoned that participants after two weeks and was it the same person than before? Did the participants know the nutritionist that visited them and was it the same person that first visited or called them?

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The readers do not necessarily know what Early Intervention for Psychosis teams are and a better description would be necessary. e.g: Do these teams exist outside the intervention? Do all the participants attend these teams also outside the intervention? How did these teams become part of the intervention, how were they recruited? What is the relationship of authors to these teams? Please do not use abbreviations.

Please write 'Kolmogorov–Smirnov test' instead of 'K-S test'.

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What were the post-hoc analyses mentioned at the end of the result section?

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At the beginning of the discussion, instead of referring to "the Psycho-Nutritional Intervention", I suggest to briefly specify the intervention content. Then, the results need to be summarised and described before proceeding to discussion of possible explanations.

"and missing data evident for baseline nutritional knowledge scores" – please clarify

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Thirdly and most importantly, it needs to be discussed if something in the MI delivery might have affected the results and

for this, a more detailed description of the intervention is needed in the methods section.

It would be also good to discuss also the limitations of the stage of change measure, e.g. collapsing heterogeneous concepts into one value. It is very different to increase intention compared to translating intention into behaviour. If the study data is still available, it would be useful to see to which extent participant move from intention phases to action phase, this would also decrease the worries about social desirability.

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In general, it would be easier to comment the study if it had row numbers.

Despite this long list of wishes to improve the clarity of the study, I want to thank the authors for conducting a demanding and important intervention and for bringing the results into scientific debate.

Close

Review Form Response

Empirical Paper

This review form consists of two sections. This first section is intended as a tool to quickly inspect the required and optional components of this submission. The second section contains the actual review.

Section 1a, Full Disclosure: Replication Package:

Note that for any of these elements, an explanation by the authors as to why this element is omitted, also serves, that is, if the explanation is acceptable. After all, one of HPB's goals is to help emptying the file drawers, and older studies may no longer have all these resources available.

☒ **Includes protocols for recruitment of participants and guiding participants through the study**

☒ **Includes templates for communications with participants (if applicable)**

☒ **Includes operationalisations of measurements (e.g. questionnaires, source code)**

☒ **Includes operationalisations of manipulations (e.g. intervention manuals, stimuli, etc)**

☒ **Includes analysis plan**

☒ **Includes proposal for ethical approval**

☒ **Includes confirmation of ethics approval/Institutional Review Board (IRB) approval**

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Section 2: manuscript iterations

This section is comprised of the manuscript preprints in anti-chronological order (i.e. the originally submitted manuscript is placed last, preceded by the revisions, with the penultimate version directly following this title page).

INTRODUCTION

Individuals with 'First Episode Psychosis' regularly consume less healthy diets than the general population (Williamson, Kilner & Clibbens, 2015; Distasquale et al., 2013). First Episode Psychosis (FEP) refers to those experiencing psychotic symptoms for the first time, in the early stage of a psychotic illness or treatment (Breitborde, Srihari & Woods, 2009). There is a growing body of thorough and experimental research suggesting the links between food and mental health. For example, a diet rich in minerals and nutrients such as omega 3 fatty acids and antioxidants, has been linked to both the prevention and amelioration of symptoms in psychiatric illnesses such as depression and schizophrenia (Firth et al., 2017; Pawelczyk et al., 2016; Peet & Stokes, 2005).

As a result of poor diets, patients with psychosis also have higher levels of obesity (Henderson et al., 2006), which in part explains the higher rates of physical illnesses such as diabetes, coronary heart disease and hypertension that account for the reduced life expectancy in this clinical group (Mann, 2002). Equally, despite their efficacy in terms of reducing symptoms, new generation anti-psychotic drugs can result in weight gain (Russell & Macke, 2001). Alongside a greater prevalence of smoking and a lack of exercise (Strassnig, Brar & Ganguli, 2006), risks to physical health are high and often neglected, with treatment focused on mental health.

Nutrition interventions in practice

Despite clear argument for nutritional therapies, putting this into practice in terms of individual behavioural change, and nutritional services to support this, has been a slow process (Amani, 2007). In the setting of this study, the mental health

nutritionist's goal is to assess current dietary practice using food diaries which are entered into a computer program (NetWISP Dietary Analysis software) to provide a break-down of nutritional consumption. Dietary advice regarding improved nutrition for mental and physical health, and not just weight loss, is given in the service user's home in verbal and written format (see Williamson, Kilner & Clibbens, 2015).

However, this information assumes individuals want and feel able to make changes having read or listened to the information provided. Changing health behaviour can be a challenge, particularly in this clinical group, who are further impeded by cognitive deficits such as poor attention and apathy resulting from the effects of medication and the illness itself (Wolf et al., 2014; Warner & Mandiberg, 2013; Lieberman et al., 2001).

There are limited studies focusing on psychosis and nutrition, especially FEP; with the majority including a range of psychotic illnesses e.g. schizophrenia. Most of the literature focuses on weight management in obese participants, rather than improved nutrition for non-obesity-related physical and mental health, excluding individuals of normal weight who would benefit from intervention. Although often coupled with increased physical activity, these interventions have demonstrated a change in eating habits (see Bonfioli et al., 2012), therefore lessons can be learned regarding potentially successful approaches to replicate in a study of healthy eating irrespective of participant weight. Effective psychological interventions for weight loss in psychosis include, amongst others, motivational interviewing (Menza et al., 2004; Baker et al, 2014); and dietetic and group practical sessions (Teasdale et al., 2016). Niv et al (2014) conducted a 16-week psycho-social weight management program for individuals with schizophrenia including psychoeducation and

behavioural techniques (not including motivational interviewing), but found no significant change in weight or Body Mass Index (BMI) in the intervention compared to the control group. Individuals with FEP exhibit lower levels of motivation (Lyne et al., 2012) which may explain, in part, the challenges to achieving desired outcomes in this clinical group.

One potential solution is the use of Motivational Interviewing (MI) (Miller & Rollnick, 2002). MI is a form of face-to-face psychological therapy which incorporates a client-centred collaborative approach in the exploration and eliciting of behaviour change, actively resolving ambivalence without an authoritarian approach. MI encourages reflection and the generation of problem-solving strategies, emphasising personal choice and control. Interventions may consist of one brief meeting (5-10 minutes) or a formal session (1- 2 hours), with the number of sessions offered depending on the goal (health behaviour) and individual needs (Martins & McNeil, 2009). In practice it includes, amongst other techniques: using open-ended questions, building rapport, working as a collaborator, recognising the normality of having mixed feelings and providing feedback. Meta-analyses suggest that even a brief 15 minute session of MI results in a significant effect for a broad range of behavioural problems, in 64% of studies analysed (Rubak et al., 2005).

In a systematic review and meta-analysis (Olker et al., 2016), 12 of the 14 interventions included MI; and these were statistically more effective than a control at achieving weight loss, however no studies reached clinically significant levels (5% weight reduction). Using MI with individuals with FEP may prove more challenging. Adherence and engagement may be compromised owing to the nature of a

psychotic illness and symptoms (Barkhof et al., 2006). Therefore adaptations may be necessary for this clinical group.

The aim of this pilot study was to assess the potential efficacy of a brief face-to-face motivational interviewing based intervention for enhancing 'readiness to change eating behaviours' (Intervention Group). The intervention is based on Miller & Rollnick (2002) and intervention manuals from previous studies (e.g. Alvarez-Jiménez et al., 2006), but was also adapted with the inclusion of behaviour change techniques presented to meet the cognitive needs of young people with first episode psychosis using visual aids and a novel workbook (see Replication Package). 'Readiness to change' refers to an individual's willingness to undertake a given behaviour in a given time period (Ceccarini et al., 2015).

METHODS

Design

A longitudinal, part randomised controlled trial design was used for this pilot study, comprising three groups: i) Control group (who received no nutritional advice or input); ii) Usual Care (standard nutritional therapy only which included a nutritional assessment and advice on dietary change from the team nutritionist; and iii) and the Motivational Interviewing (MI) intervention. Three arms were compared to establish whether usual care offered similar benefits to the intervention group. Differences in pre- and post 'Readiness to Change' healthy eating habits were compared between these groups, and over three time points: Time 1 (Baseline), Time 2 (one month post intervention) and Time 3 (three months post intervention). A fully randomised

controlled trial was not possible due to insufficient numbers of service users for 3 groups in one of the Early Intervention for Psychosis teams (EIPT) where standard nutritional therapy is offered. One EIPT did not offer nutritional therapy at the time, therefore acted as a control group. In the other EIPT, service users were randomised to either the usual care or Intervention group. The two teams had very similar models of service provision as they are managed by the same National Health Service (NHS) mental health trust, however were in different geographical locations in the north of England.

EIPT's are multi-disciplinary, UK-wide community based NHS mental health teams providing medical, practical and psychological care, usually within the service user's home over a three year period; to young people (usually up to 35 years of age), experiencing symptoms of psychosis (e.g. paranoid delusions, hallucinations). As part of this particular service, a nutritionist was employed to offer advice and support regarding nutrition.

Sampling

Participants were community dwelling service users of 3 EIPT's in the north of England, UK. All participants had been diagnosed with a FEP and were currently receiving psycho-social support and anti-psychotic medication from the team. They had all been seen at least once by the team nutritionist and offered dietary advice, but had not received any form of behavioural intervention to enhance healthy eating behaviour. Service users were excluded from the study if they were too unwell to take part (e.g. lacked mental capacity, as assessed by the team Psychiatrist) or

became unwell after they had provided consent; their speech and comprehension of the English language was limited or they had learning disabilities.

Procedure

The Information sheet, questionnaires and intervention were discussed with the team and adapted and piloted with 6 ex-service users attending a carers group. All service users meeting the inclusion criteria in the control group (N=53), and Intervention and Usual care groups (N=97) were invited to take part in the study by their care co-ordinator, and given an invitation letter, information sheet and written consent form to sign. Those who agreed to take part were asked to complete a short 6-item questionnaire, with support from staff if needed, regarding their current eating habits (e.g. level of fruit, vegetable and fibre intake, consumption of high unsaturated fat, salt and refined sugary foods) to exclude those with existing healthy and well-balanced diets. The decision to exclude was made by the nutritionist who reviewed the questionnaires and consulted the service users and/or staff for clarification if necessary. Seventy-six participants agreed to take part. Only three service users were deemed to have sufficiently balanced diets that did not require intervention, and these were screened out at this stage. All participants were blinded to the outcome of randomisation as all were told that they would receive the intervention at some point (wait-list control) over an 18 month period. In the EIPT that was to include the intervention and control groups, those who had agreed to take part (N=72), were each given a number in a computer program database and randomly assigned to either the usual care or intervention group. Participants in these groups received the intervention after the study was completed. All

participants were given questionnaires by staff in their own homes to complete at Time 1 (T1), 1 month post intervention at Time 2 (T2), and 3 months later at Time 3 (T3). Demographic information was collected at baseline. Although weight and height were measured, BMI was not calculated and is no longer possible due to a lack of access to the raw data.

Operationalisations

Manipulations

The study intervention was a brief one-off individual face-to-face MI intervention utilising a series of 'Behaviour Change Techniques' (BCT's) (Michie et al., 2013). Although following the structure and principles of existing MI interventions, it was adapted into as a series of written and visual tasks within a workbook. Although not coded as such at the time, the BCT's included (amongst others): *'Goal Setting (behaviour)'; 'Action Planning'; 'Information about Health Consequences'; 'Instruction on how to perform the behaviour'; 'Self-monitoring of Behaviour'; 'Feedback on Behaviour' and 'Prompts/Cues'*. The facilitator utilised the Motivational Interviewing counselling style to guide the process of working through the workbook. The intervention was developed with input from two health Psychologists, six service users and the nutritionist. Service users commented on content, presentation and ease of comprehension of the intervention, leading to revision. The intervention took place in the service user's home, lasted approximately 1 hour and was conducted by a psychologist trained in MI, recently employed by the team, who was not previously known to the service users. MI techniques were used to facilitate change talk and address the pros and cons of

change. Visual aids within the intervention workbook were used to overcome problems relating to attention and memory, and also to ensure fidelity to intervention content to ensure each participant received the same intervention. Small goals were set and a feedback card given. Service users were telephoned by the psychologist approximately two weeks later to assess progress. In the interim period they were visited by the team nutritionist, who offered ongoing encouragement and answered questions about healthy dietary change.

Measures

Participant ethnicity, height, weight and the length of time they had been seen by the EIPT was collected at baseline to ascertain whether differences existed across the three groups that might influence the findings. Weight was not compared across time points as the goal of the intervention was improved healthy eating, rather than weight loss. As a result intention or 'Readiness to Change' behaviour was measured as follows:

(i) *'Readiness to Change Eating Habits Scale'*. This 20- Item measure includes questions based on the 5 'Stages of Change' a person is in at any given time, in terms of healthy eating (e.g. 'Pre-contemplation, Contemplation, Preparation, Action or Maintenance'). It is based on the 'Transtheoretical Model' (Prochaska & DiClemente, 1982; 1986); and the scale is adapted from the 'University of Rhode Island Change Assessment (URICA) Weight Control Long Form' (McConaughy, Prochaska, & Velicer, 1983). Responses to items are recorded on a 5-point Likert scale ranging from 'Strongly Disagree' to 'Strongly Agree'. A 'Readiness to Change Eating Habits' score is calculated based on adding scores from items relating to 'active' stages

(Contemplation, Planning, Action and Maintenance) and subtracting the 'Inactive' stage item scores (Pre-contemplation). Scores range from a possible 20 to 100, with greater scores representing a greater readiness to change behaviour. 'Variation in Readiness to Change Eating Habits' score over time was calculated by subtracting T1 scores from T2 (T2-T1) and T3 (T3-T1) scores.

(ii) '*Nutritional Knowledge Questionnaire*'. This 27-Item measure (see supplementary file 1) was developed specifically for the study by the team nutritionist, to measure participants' nutritional knowledge. Although measures currently exist, none were deemed appropriate for this specific clinical group when reviewed by the nutritionist and team Psychiatrist; due to the time taken to complete, language used and level of difficulty. However aspects of existing measures were simplified. The new measure consisted of 3 subscales, including statements such as '*Eating an unhealthy diet can lead to which of the following?*' and 'True' or 'False' statements such as '*To have a healthy diet everything you eat needs to be low fat*'. The measure was piloted with 6 service users and amended accordingly. Overall scores were based on the sum of correct answers.

Power Analyses

Due to the difficulties of recruiting from this clinical population, a target of 90 service users was deemed realistic for a pilot, based on sample sizes obtained in previous research (Alvarez-Jimenez et al., 2008).

Data collection period

Data collection took place between November 2007 and March 2009.

Statistical Analysis

Data was entered and analysed in the Statistical Package for the Social Sciences (SPSS). To establish whether the data was normally distributed, histograms were created, Skewness and Kurtosis calculated, and a Kolmogorov-Smirnov test performed, to ascertain whether non-parametric versions were required. Factorial ANOVA (3 x 3 model) was used to look for differences in readiness to change scores over the time points, across groups. Significant differences in ethnicity across groups was assessed using the Mann-Whitney U test, and Time seen by the EIPT team was compared using an Independent Samples T-Test, as data for this variable was not available from the control group. A one-way ANOVA was conducted to establish whether there were any differences in nutritional knowledge at baseline between the 3 groups. As the analysis throughout included 3 groups, the effect size was calculated using Eta Squared (η^2) rather than Cohen's d. Missing data was minimal and when present, was excluded from the analysis on an item rather than case basis.

Ethics

Ethical approval was obtained from the National Research Ethics Service Committee for South Yorkshire.

RESULTS

Descriptive Statistics

A total of 73 participants took part in the study. At Time 1, this included 30 in the intervention group, 21 in the usual care group, and 22 in the control group. A total of 50 took part at Time 1 and Time 2, and 16 at all three time points. Attrition rates are illustrated in Table 1. Nine participants in the control group declined to complete the nutritional knowledge questionnaire, therefore data was missing for this item (see Table 3). The Kolmogorov-Smirnov Test for normality within the data showed that the Nutrition Knowledge total scores and gender variables were not normally distributed ($p < .001$), therefore a non-parametric test (Kruskal-Wallis) was used.

Demographic characteristics

There were no significant differences between age ($F(2,70) = .781$, $p = .462$, $\eta^2 = .022$), height ($F(2,50) = .541$, $p = .585$, $\eta^2 = .021$) and gender ($\chi^2(2) = .735$, $p = .692$, $\eta^2 = 0.010$); between the intervention, usual care and control groups (see Table 2). Due to an unforeseen lack of access to medical information, it was not possible to collect data relating to ethnicity and the time seen by the EI team from the control group, however no differences existed between the intervention and usual care groups for time seen by the EI team ($t(48) = -1.214$, $p = .213$) and ethnicity ($U = 249.00$, $p = .057$). The sample was predominantly 'White British' (82.4%). Significant differences were found between the groups in terms of weight at baseline ($F(2,50) = 3.468$, $p = .039$, $\eta^2 = .122$). The mean scores indicated that the intervention group ($m = 87.4\text{kg}$, $SD = 24.54$) consisted of individuals with a greater weight than the usual care group ($m = 72.9\text{kg}$, $SD = 16.28$), and control group ($m = 68.8\text{kg}$, $SD = 22.17$).

Nutritional Knowledge

There were no significant differences observed in nutritional knowledge total scores at baseline across the three groups (see Table 3) ($\chi^2(2)=.061$, $p=.970$, $\eta^2=.001$). In general knowledge about nutrition was deemed by the nutritionist to be relatively good, although no normative comparisons were made. For example 61.9% of all participants recognised that sardines were a good source of omega 3, and 80.6% knew that this fatty acid is important for mental as well as physical health. The majority knew that obesity can lead to heart disease and diabetes (93.5% and 85.2% respectively), and that unhealthy foods can affect memory and concentration (80.6%); and tiredness (lethargy) (85.5%).

Readiness to Change Eating Habits and variation in scores over time

There were no significant differences in baseline (T1) Readiness to Change Eating Habits between the 3 groups (see Table 4) ($F(2,60)=.054$ $p=.947$, $\eta^2=.002$). A 3 x 3 factorial ANOVA was conducted to compare the main effects of 'Time point' and 'Treatment Group' and the interaction between these factors on Readiness to Change scores. There was no significant main effect for Time ($F(2,15)=.722$, $p=.637$) or Group ($F(2,15)=.042$, $p=.959$); and no significant interaction between these two factors ($F(2,15)=.292$, $P=.934$). It was not possible to calculate Eta Squared scores for the factorial ANOVA as the raw and output data was no longer available at the time of writing.

There were no significant differences in Variance in Readiness to Change (T3-T1) scores ($F(2,12)=.558$, $p=.586$, $\eta^2=.085$); and Variance in Readiness to Change scores (T2-T1) ($F(2,39)=.730$, $p=.488$, $\eta^2=.036$), although the means revealed a greater increase in the Usual Care group (see Tables 5 & 6). The variance in mean

Readiness to Change scores between T1 and T2 (T2-T1), suggests the intervention group had the greatest range of mean scores, with both the most progression in terms of readiness for some participants, and the most regression for others (see Fig. 1).

DISCUSSION

This study sought to pilot a brief face-to-face motivational interviewing based intervention for improving readiness to change eating habits in young people with FEP; compared to a usual (nutritional) care and control group. Thirty service users received the Intervention group, although attrition rates were high over time, and missing data present in the baseline nutritional knowledge data. Almost all the service users had a good basic nutritional knowledge at baseline, therefore it is plausible that poor eating behaviours were not principally due to a lack of knowledge, supporting the need for an intervention that offers more than nutritional information.

The intervention did not significantly increase readiness to change eating habits over and above the usual care and control groups. The brief nature of the intervention may have been insufficient to support change, and responses may be biased, illustrating what individuals hope, rather than can actually achieve. Nonetheless, an interesting finding is that the intervention group had the greatest progression (or increase) in Readiness to Change between T1 and T2 for some participants (although this was only slightly greater than the usual care group); and also the most regression (reduction) for others. Therefore the intervention had the most positive effect for some individuals, but the exact opposite for others, reducing

their readiness to change and seemingly more detrimental than if they had not received the intervention at all. However, caution should be given as this represents only the range rather than frequency of scores. One potential explanation is that in removing the psychological and practical barriers to change, individuals lose the justification for not changing their behaviour, and if still they feel unable or try and 'fail', might resolve this unease by committing to being even less 'ready to change', as a potential self-protective mechanism.

The MI intervention may be both beneficial for some, and detrimental for others, suggesting the potential need for further exploration of this phenomenon. As the usual care group exhibited a similar (albeit slightly smaller) overall progression in readiness scores compared to the intervention group, *but* less regression, it is possible that this intervention is more effective overall, as it poses less risk of discouraging some individuals, making them even less ready to change their eating habits. A more robust evaluation is required to explore this further. Clearly conclusions from this data must be cautious given the small sample size and limitations of the methodology. Caution should also be taken in generalising to all psychotic disorders (e.g. schizophrenia), as the length of illness, symptomology and medication may influence the findings.

Nevertheless the potential to develop and tailor motivational interviewing interventions to this clinical group warrants further research. Qualitative exploration with service users regarding intervention content, mode of delivery, additional support, timing and dose to optimise effectiveness would be advantageous. Evidence suggests individuals in the later stages of treatment for psychosis have less

motivation (Luther et al, 2015), suggesting the need to target interventions in a timely manner.

Limitations

There are a number of evident limitations with the study. The sample was predominantly white British, and although a reasonable size given the clinical group, likely to be heterogeneous in terms of confounding variables that were not accounted for in a covariate analysis. Power to establish an effect would also have been enhanced had comparisons been made between two rather than three experimental groups. and the study lacked the true randomisation of a randomised controlled trial. The addition of a pre-post nutritional assessment of eating habits would have demonstrated whether a relationship existed between readiness to change eating habits and actual eating behaviour. The control group consisted of newer patients who may have been in an earlier stage of illness, which might have contributed to the null finding but was not assessed as data about 'Time seen by EIPT' was not collected for this group. An increase in readiness to change in the control group as well as the other two groups may have resulted from social desirability effects or from the prompt to change eating habits made simply by study participation.

Significant differences in weight at baseline were observed between groups. This could have affected the results due to differing levels of motivation, previous attempts to change eating behaviour which may or may not have been successful, the role of anti-psychotic induced weight gain and the cognitive impact, and the psychosocial effects of being over-weight which could have affected outcomes. As

mean height was greatest in the intervention group it is possible that this explains the greater mean weight. A lack of BMI measurement is another limitation of the study. Further post-hoc analyses were also not possible as access to study data was no longer possible when the first author ceased employment.

Other methodological limitations include potential randomisation bias in the control group; and due to the high attrition rates, the removal of T3 data and re-analysis may have produced more robust and alternative findings. Finally the use of a 'Readiness to Change' measure is much debated, regarding whether change can be deemed linear, with arguments that many mechanisms of change are involved; and other measures, such as self-efficacy, might be more appropriate (Lenio, 2006).

Assisting individuals to change health-related behaviours, especially in this clinical group, is a difficult and complex process. Some of the limitations in this study were indicative of conducting research in a time-, staff- and financially constrained healthcare environment, where unforeseen barriers challenged the progress of an unfunded pilot. Even with the skills of motivational interviewing at play, some participants in this study presented with low mood and apathy, consistent with the symptoms of psychosis, and high attrition rates are to be expected when conducting research with participants with severe mental illness.

There are factors specific to FEP including the impact of symptoms and medication on attention, memory and concentration (cognitive deficits) that could impede the effectiveness of an MI intervention in this clinical group. Fiszdon et al (2016) suggest the need to incorporate simple adjustments, including more structure, repeating and summarising content and using visual aids where possible. This is supported by Rüsç & Corrigan (2002), who suggest the MI process is

simplified into smaller steps, limiting demand on memory and attention. The intervention in this study utilised similar approaches, but would have benefitted from qualitative exploration with participants to explore their views about this and how it could be improved. Given more recent knowledge about the most effective behaviour change techniques (BCT's) for healthy eating (e.g. Michie et al, 2011), the intervention would also be improved by considering which BCT's are more appropriate for this group also.

The current principal focus on diet solely in the context of obesity is dangerously neglecting individuals of a healthy weight, with poor diets. Future intervention development needs to redirect targets to include this group, and consider how best to adapt methods such as MI, to better meet their specific needs.

CONCLUSIONS

The assumption that brief MI will have either a positive or neutral effect, may be erroneous. Due to the methodological limitations of this study, no conclusions can be drawn, however further exploration of this phenomena is warranted. Future research would benefit from exploring the exact nature of using MI approaches for improved nutrition with people with first episode psychosis, and whether careful assessment of appropriateness and tailoring to overcome cognitive deficits associated with the illness and treatment is necessary, ensuring interventions are offered to those most likely to benefit.

ACKNOWLEDGEMENTS

The authors wish to thank the service users who took part in the research, and the staff at Rotherham, Doncaster and South Humber HNS Mental Health Foundation Trust for supporting the work.

DECLARATION OF CONFLICTING INTERESTS

The authors declare that there is no conflict of interest.

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Table 1. Attrition rates over the three time points.

	Time 1	Time 2 (% attrition from Time 1)	Time 3 (% attrition from Time 1)
Intervention	30	25 (17)	6 (76)
Usual care	21	16 (24)	6 (63)
Control	22	9(59)	4(56)

Table 2. Demographic characteristics of the three groups at T1.

	Intervention	Usual care	Control
<i>Gender (males)</i>	20	15	13
	18-33	18-32	18-29
<i>Age (years)</i>	(Mean = 23.90)	(Mean = 23.90)	(Mean = 22.50)
<i>Ethnicity</i>			
<i>White British</i>	27	15	n/a
<i>Asian British</i>	3	1	n/a
<i>Asian</i>	2	2	n/a
<i>Chinese</i>	1	1	n/a
<i>White European</i>	2	2	n/a
<i>Weight at baseline</i>	51-126	48-108	42.70-108
<i>range (kg)</i>	(Mean = 87.36)	(Mean = 72.944)	(Mean = 68.81)
	152-203	155-188	157-183
<i>Height range (cm)</i>	(Mean = 173.90)	(Mean = 171.158)	(Mean = 169.20)
<i>Time seen by EI</i>			
<i>Team range</i>	6-39	5-69	n/a
<i>(months)</i>	(Mean = 20.77)	(Mean = 25.16)	

Table 3. Comparison of mean and standard deviation (SD) Nutritional Knowledge total scores between groups at baseline (T1) and non-parametric Kruskal-Wallis Test. *Data for this outcome was missing for 9 participants in the control group who declined completion.

	N	Mean	SD
Intervention	30	19.00	5.942
Usual care	21	19.62	4.031
Control	13*	20.08	3.570

Table 4. Comparison of mean and standard deviation (SD) Readiness to Change Eating Habits scores between groups and across time points

		Time 1	Time 2	Time 3
	N	Mean (SD)	Mean (SD)	Mean (SD)
Intervention	30	9.733(2.67)	11.167(1.401)	11.167(5.492)
Usual care	21	9.548(2.47)	11.833(4.622)	11.167(5.192)
Control	22	9.833(2.63)	11.067(4.044)	11.533(4.998)

Table 5. Comparison of the mean and standard deviation (SD) Variation in Readiness to Change (T2-T1) scores between groups.

	N	Mean	SD
Intervention	25	1.750	3.993
Usual care	16	2.539	4.378
Control	9	.1667	2.691

Table 6. Comparison of the mean and standard deviation (SD) Variation in Readiness to Change (T3-T1) scores between groups.

	N	Mean	SD
Intervention	6	2.208	4.010
Usual care	6	2.041	2.624
Control	4	4.500	3.969

Figure 1. Graph indicating the range in degree of positive change (progression) and negative change (regression) in Readiness to Change scores between T1 and T2 by group across all participants.

INTRODUCTION

Individuals with psychosis (First Episode Psychosis, Schizophrenia or Schizo-affective Disorders) regularly consume less healthy diets than the general population (Williamson, Kilner & Clibbens, 2015; Dapasquale et al., 2013). There is a growing body of thorough and experimental research suggesting the links between food and mental health. For example, a balanced diet rich in minerals and other nutrients such as omega 3 fatty acids and antioxidant vitamins C and E, has been linked to both the prevention and amelioration of symptoms in psychiatric illnesses such as depression and schizophrenia (Firth et al., 2017; Pawelczyk et al., 2016; Peet & Stokes, 2005).

As a result of poor diets, patients with schizophrenia also have higher levels of obesity (Henderson et al., 2006), which in part explains the higher rates of physical illnesses such as diabetes, coronary heart disease and hypertension that account for the reduced life expectancy and higher (non-suicide) mortality rates in this clinical group (Mann, 2002). Equally, despite their efficacy in terms of reducing symptoms, the new generation of anti-psychotic drugs can result in weight gain (Russell & Macke, 2001). Alongside a greater prevalence of smoking and a lack of exercise (Strassnig, Brar & Ganguli, 2006), risks to physical health are high and often neglected, with treatment focused on mental health.

Nutrition interventions in practice

Despite clear argument for nutritional therapies, putting this into practice in terms of individual behavioural change, and nutritional services to support this, has been a slow process (Amani, 2007). In the setting of this study, the nutritionist's goal has

been to assess current dietary practice using food diaries which are then entered into a computer program (NetWISP Dietary Analysis software) to provide a breakdown of an individual's consumption of total energy, sugar, total fat, saturated fat, protein, carbohydrate, vitamins and various minerals. Dietary advice regarding improved nutrition for overall mental and physical health, and not just weight loss, is then given in the service user's home in verbal and written format (see Williamson, Kilner & Clibbens, 2015). However, this information assumes individuals want and feel able to make changes having read or listened to the information provided. Changing health behaviour can be a challenge, but particularly in a clinical group where putting information into practice may be further impeded by cognitive deficits such as poor attention and apathy resulting from the effects of medication and the illness itself (Wolf et al., 2014; Warner & Mandiberg, 2013; Lieberman et al., 2001).

The majority of the literature relating to psychosis and nutrition focuses on weight management in obese participants, rather than improved nutrition for non-obesity-related physical and mental health, excluding individuals of normal weight who could benefit from intervention. Although often coupled with increased physical activity, these interventions have demonstrated a change in eating habits (see Bonfioli et al., 2012), therefore lessons can be learned regarding potentially successful approaches to replicate in a study of healthy eating irrespective of participant weight. Effective psychological interventions for weight loss in schizophrenia and related disorders include, amongst others, motivational interviewing (MI) (Menza et al., 2004; Baker et al., 2014); and dietetic and group practical sessions (Teasdale et al., 2016). In a systematic review and meta-analysis (Olker et al., 2016), interventions offering

individual sessions of Motivational Interviewing early after diagnosis were the most effective at achieving weight loss in participants, however no studies reached clinically significant levels of weight loss. Niv et al (2014) conducted a 16-week psycho-social weight management program for individuals with schizophrenia including psychoeducation and behavioural techniques (not including motivational interviewing), but found no significant change in weight or Body Mass Index (BMI) in the intervention compared to the control group who did not receive the intervention (treatment as usual). Individuals with psychosis and schizophrenia exhibit lower levels of motivation (Lyne et al., 2012) which may explain, in part, the challenges to achieving desired outcomes in this clinical group.

Motivational Interviewing (MI) (Miller & Rollnick, 2002) is a form of face-to-face psychological therapy which incorporates a client-centred collaborative approach in the exploration and eliciting of behaviour change. It helps to guide participants to actively resolve the ambivalence that they have towards behaviour change without an authoritarian approach. MI encourages reflection and the generation of problem-solving strategies, emphasising personal choice and control in the process. Interventions may consist of one brief meeting (5-10 minutes) or a formal session (1-2 hours), with the number of sessions offered depending on the goal and needs of the individual. In practice it includes, amongst other techniques and strategies: using open-ended questions, building rapport, working as a collaborator, recognising the normality of having mixed feelings, providing feedback with permission. Advice is offered sparingly, because MI focuses on individuals forming their own conclusions rather than being directed in what to do.

Using MI with individuals with psychosis may prove more challenging than with the general population or other clinical groups. Adherence and engagement may be compromised owing to the nature of a psychotic illness and symptoms (Barkhof et al., 2006). Nonetheless, MI offers a tailored program that aims to 'roll with resistance', exploring ambivalence and the nature of any apathy in a non-judgmental way. Therefore it may be particularly suitable for this clinical group.

This study aimed to assess the feasibility of a brief face-to-face 'Psych-Nutritional' (PNI) Motivational Interviewing (MI) intervention for enhancing readiness to change eating behaviour, in young people with psychosis.

METHODS

Design

A longitudinal, part randomised controlled trial design was used for this feasibility study, comprising three groups: Control group (who received no nutritional advice or input), Standard Nutritional Therapy only (assessment and advice on dietary change from a nutritionist) and the 'Psych-Nutritional Intervention' (PNI). Three arms were compared to establish whether standard nutritional therapy offered similar benefits to the enhanced PNI intervention. Differences in pre- and post 'Readiness to Change' healthy eating habits were compared between these groups, and also within the same group over three time points: Time 1 (Baseline), Time 2 (one month post intervention) and Time 3 (three months post intervention). A fully randomised controlled trial was not possible due to insufficient numbers of service users for 3

groups in one of the Early Intervention for Psychosis teams (EIPT) where standard nutritional therapy is offered. One EIPT (EIPT1) did not offer nutritional therapy at the time, therefore acted as a control group. In the other EIPT (EIPT 2) service users were randomised to either the TAU or PNI groups. The two teams have very similar models of service provision as they are managed by the same National Health Service (NHS) mental health trust, however they are in different geographical locations in the north of England.

Sampling

Participants were community dwelling service users of 3 EIPT's in the north of England, UK. All participants had been diagnosed with a First Episode of Psychosis and were currently receiving psycho-social support and anti-psychotic medication from the team. EIPT see service users between the ages of 18 and 35 years of age, usually living at home. Food purchase and preparation was in the control of participants or a family member. Service users were excluded from the study if they were too unwell to take part (lacked mental capacity) or became unwell after they had provided consent; their speech and comprehension of the English language was limited or if they had learning disabilities.

Procedure

The Information sheet, questionnaires and intervention were discussed with the multidisciplinary EI team and adapted and piloted with 6 ex-service users attending a carers group. All service users meeting the inclusion criteria in EIPT 1 (control group) (N=53), and EIPT 2 (PNI and TAU groups) (N=97) were invited to take part in the

study by their care co-ordinator, and given an invitation letter, information sheet and written consent form to sign. Those who agreed to take part were asked to complete a short 6-item questionnaire, with support from staff if needed, regarding their current eating habits (e.g. level of fruit, vegetable and fibre intake, consumption of high unsaturated fat, salt and refined sugary foods) to exclude those with existing healthy and well-balanced diets. The decision to exclude was made by the nutritionist who reviewed the questionnaires and consulted the service users and/or care co-ordinators for clarification if necessary. Seventy-six participants agreed to take part. Only three service users were deemed to have sufficiently balanced diets that did not require intervention, and these were screened out at this stage. All participants were blinded to the outcome of randomisation as all were told that they would receive the intervention at some point (wait-list control) over an 18 month period. In Rotherham those who had agreed to take part in the study and to the process of randomisation (N=72), were each given a number in a computer program database and then randomly assigned to either the TAU or PNI group. Participants in the control group (from EIPT 1) and the TAU group (from EIPT 2) received the PNI intervention after the study was completed. All participants were given questionnaires by staff in their own homes to complete at Time 1 (T1), 1 month post intervention at Time 2 (T2), and 3 months later at Time 3 (T3). Demographic information was collected at baseline.

Operationalisations

Manipulations

The Psych-Nutritional Intervention (PNI) took place in the service user's home, lasted approximately 1 hour and was conducted by a researcher trained in MI, who was not previously known to the service users. Motivational interviewing techniques were used to facilitate change talk and address the pros and cons of change. The process was collaborative in nature, and multiple methods of presenting the information, including visual aids were used to overcome issues in relation to attention and memory. Small goals were set and a feedback card given. Service users were telephoned approximately two weeks later to assess progress. In the interim period they were visited by the nutritionist who offered ongoing encouragement and answered questions about dietary change and healthy eating.

Measures

Participant weight and height was collected at baseline to ascertain whether differences existed across the three groups that might influence the findings. Weight was not compared across time points as healthy eating, rather than weight loss was the goal of the intervention. As a result intention or 'readiness' to change behaviour was measured as follows:

(i) *'Readiness to Change Eating Habits Scale'*. This 20- Item measure identifies which 'Stage of Change' a person is in, in terms of healthy eating, based on the 'Transtheoretical Model' (Prochaska & DiClemente, 1982; 1986); and adapted from the 'University of Rhode Island Change Assessment (URICA) Weight Control Long Form' (McConaughy, Prochaska, & Velicer, 1983). 'Readiness to Change Eating Habits' is calculated based on adding scores on 'active' stages (Contemplation, Planning, Action and Maintenance) and subtracting the 'Inactive' stage (Pre-

contemplation). The higher the score the greater the individual's readiness to change their eating habits. 'Variation in Readiness to Change Eating Habits' score over time was calculated by subtracting T1 scores from T2 (T2-T1) and T3 (T3-T1) scores.

(ii) '*Nutritional Knowledge Questionnaire*'. This 27-Item measure (see supplementary file 1) was developed specifically for the study by a nutritionist, to measure participants' nutritional knowledge. Although measures currently exist, none were deemed appropriate for this specific clinical group when reviewed by the nutritionist and team Psychiatrist, due to the time taken to complete, language used and level of difficulty. However aspects of existing measures were simplified. The new measure consisted of 3 subscales. In the first 11 items, participants were given statements such as '*Eating an unhealthy diet can lead to which of the following?*' and asked to choose from 4 possible answers, which varied by question. The second subscale of 15 items included 'True' or 'False' statements such as '*To have a healthy diet everything you eat needs to be low fat*'. The final single item gave a pie-chart representation of a healthy balanced diet and participants were requested to choose which diagram was correct. The measure was piloted with 6 service users to assess level of difficulty and the language used, from which it was amended accordingly. Participants were each given an overall score based on the sum of correct answers.

Power Analyses

Similar studies have not measured readiness to change eating habits in this population, therefore it was not possible to reliably estimate an expected effect size for the purposes of sample size calculation. According to Cohen (1992)

approximately 21 participants would be deemed necessary to detect a large effect between the 3 groups (ANOVA), with an alpha of 0.05. However the assumption of a large effect size implies a large change in readiness to change eating habits which may be optimistic. Due to the difficulties of recruiting from this clinical population, a target of 90 service users was deemed realistic for a pilot, based on sample sizes obtained in previous research (Alvarez-Jimenez et al., 2008).

Data collection period

Data collection took place between November 2007 and March 2009.

Statistical Analysis

To establish whether the data was normally distributed, histograms were created, Skewness and Kurtosis calculated, and a K-S test performed, to ascertain whether non-parametric versions were required. Factorial ANOVA (3 x 3 model) was used to look for differences in readiness to change over the time points, across groups.

Ethics

Ethical approval was obtained from the National Research Ethics Service Committee for South Yorkshire.

RESULTS

Descriptive Statistics

A total of 73 participants took part in the study. At Time 1, this included 30 in the PNI group, 21 in the TAU group, and 22 in the control group. A total of 50 took part at

Time 1 and Time 2, and only 16 took part at all three time points. Attrition rates are illustrated in Table 1. Nine participants in the control group declined to complete the nutritional knowledge questionnaire, therefore data was missing for this item (see Table 3).

Demographic characteristics

There were no significant differences between age, gender and height between the PNI, TAU and Control groups (see Table 2). Due to an unforeseen lack of access to medical information for the control group, it was not possible to collect data relating to ethnicity and the time seen by the EI team from the control group, however no differences existed between the PNI and TAU groups. Significant differences were found between the groups in terms of weight at baseline ($F=3.468$, $df=2$, $P < .05$). The mean scores indicated that the PNI group ($m=87.4\text{kg}$, $SD=24.54$) consisted of individuals with a greater weight than the TAU group ($m=72.9\text{kg}$, $SD=16.28$), and control group ($m= 68.8\text{kg}$, $SD=22.17$).

Nutritional Knowledge

The K-S Test for normality within the data showed that the Nutrition Knowledge total scores variables were not normally distributed ($p<.001$), therefore a non-parametric test (Kruskall-Wallis) was used. There were no significant differences observed in nutritional knowledge total scores at baseline across the three groups (see Table 3). In general knowledge about nutrition was relatively good, although no normative comparisons were made. For example 61.9% of all participants recognised that sardines were a good source of omega 3, and 80.6% knew that this fatty acid is

important for mental as well as physical health. The majority knew that obesity can lead to heart disease and diabetes (93.5% and 85.2% respectively), and that unhealthy foods can affect memory and concentration (80.6%), and tiredness (lethargy) (85.5%).

Readiness to Change Eating Habits and variation in scores over time

There were no significant differences in baseline (T1) Readiness to Change Eating Habits between the 3 groups ($p=.947$) (see Table. 4). Over the three time points, and between the three groups, there were no significant differences in terms of Readiness to Change Eating Habits scores; Variance in Readiness to Change (T3-T1) scores; and Variance in Readiness to Change scores (T2-T1) scores, although the means revealed a greater increase in the Control group (see Table. 5). The variance in mean Readiness to Change scores between T1 and T2 (T2-T1), appears to indicate that the PNI group had the greatest range of mean scores, with both the most progression in terms of readiness, and the most regression (see Fig. 1), although this was not confirmed by post-hoc analysis.

DISCUSSION

In this study thirty service users received the Psycho-Nutritional Intervention, and it achieved a sufficient sample size to compare across three groups, although attrition rates were high over time and missing data evident for baseline nutritional knowledge scores. Almost all the service users had a good basic nutritional knowledge at baseline, therefore it is plausible that poor eating behaviours were not

principally due to a lack of nutritional knowledge, supporting the need for an intervention that offers more than nutritional information and guidance.

Readiness to change

The unexpected finding that the Control group exhibited change over time as well as the PNI and TAU group might be explained in a number of ways. Social desirability effects may have played a role, the brief nature of the PNI may have been insufficient to support sufficient change, and responses may be biased, illustrating what individuals 'hope', rather than can actually achieve. Nonetheless, an interesting finding is that the PNI group had the greatest progression (or increase) in Readiness to Change between T1 and T2 for some participants (although this was only slightly greater than the TAU group); and also the greatest regression (reduction) for others. Therefore the intervention had the most positive effect for some individuals, but the exact opposite for others, reducing their readiness to change and seemingly more detrimental than if they had not received the intervention at all. Evidently the intervention may be both therapeutic for some, and anti-therapeutic for others, suggesting the potential need to assess who receives it. As the TAU group exhibited a similar (albeit slightly smaller) overall progression in readiness scores compared to the PNI group, *but* less regression, it is possible that this intervention is more effective overall, as it poses less risk of reducing readiness and putting off some individuals, making them even less ready to change their eating habits. A more robust evaluation is required to explore this further. Clearly conclusions from this data must be cautious given the small sample size and limitations of the methodology, nevertheless the potentially anti-therapeutic effect of motivational

interventions in this context, and assessing who is offered them, warrants further exploration.

Limitations

There are a number of evident limitations with the study. The sample size was reasonable given the clinical group, however likely to be heterogeneous in terms of confounding variables that were not accounted for in a covariate analysis. Power to establish an effect would also have been enhanced had comparisons been made between two rather than three experimental groups. The study also lacked the true randomisation of a Randomised Controlled Trial. The addition of a pre-post nutritional assessment of eating habits would have demonstrated whether a relationship existed between readiness to change eating habits and actual eating behaviour. The Control group consisted of newer patients who may have been in an earlier stage of illness, which might have contributed to the null finding and could not be assessed as data about 'Time seen by EIPT' was not collected for this group. A positive increase in readiness to change in the control group may have resulted social desirability effects or from the prompt to change eating habits made simply by study participation.

Significant differences in weight at baseline were observed between groups. This could have affected the results in a number of ways, due to differing levels of motivation, previous attempts to change eating behaviour which may or may not have been successful, the role of anti-psychotic induced weight gain and the cognitive impact, and the psychosocial effects of being over-weight which could have

affected outcomes. As mean height was greatest in the PNI group, it is possible that this explains the greater mean weight. Measuring BMI would therefore have overcome this issue. Unfortunately post-hoc analyses were not possible as access to study data, was no longer possible when the first author ceased employment.

Other methodological limitations include potential randomisation bias, for example Manchester EIPT participants may have guessed they were in the control group, by virtue of the waiting time, which may explain the higher attrition in this group. Due to the high attrition rates, the removal of T3 data and re-analysis may have produced more robust and alternative findings. Assisting individuals to change health-related behaviours, especially in this clinical group, is a difficult and complex process. Some of the limitations in this study were indicative of conducting research in a time-, staff- and financially constrained healthcare environment, where unforeseen barriers challenged the progress of an unfunded pilot. Even with the skills of motivational interviewing at play, some participants in this study presented with low mood and apathy during the intervention and data collection, consistent with the symptoms of psychosis, and high attrition rates are to be expected when conducting research with participants with severe mental illness.

Implications

The intervention is designed to be brief but establishing the degree of contact for optimal results is needed. By establishing links with nutritionists and dieticians, mental health professionals can help to encourage patients and service users with psychosis to improve their nutritional intake and eating behaviours, however this

may require carefully planned, in-depth psychological interventions to support change. The current principal focus on diet solely in the context of obesity is dangerously neglecting individuals of a healthy weight, with poor diets. Future intervention development needs to redirect targets to include this group.

CONCLUSIONS

This study evaluated the efficacy of a brief face-to-face MI intervention that, unlike previous work, focuses on improved healthy eating rather than solely weight loss, for service users with psychosis. Although the intervention did not appear to be effective in improving readiness to change eating behaviour in comparison to treatment as usual and the control group, it appears the intervention was both effective for some, and anti-therapeutic for others. The assumption that brief MI will have either a positive or neutral effect, may be erroneous. Due to the methodological limitations of this study, no firm conclusions can be drawn. Nonetheless, further exploration of this phenomena is warranted. Future research would benefit from exploring the exact nature of this anti-therapeutic effect, if indeed it exists; what causes it, and how careful assessment might reduce the incidence, ensuring interventions are offered to those most likely to benefit.

ACKNOWLEDGEMENTS

The authors wish to thank the service users who took part in the research, and the staff at Rotherham, Doncaster and South Humber HNS Mental Health Foundation Trust for supporting the work.

DECLARATION OF CONFLICTING INTERESTS

The authors declare that there is no conflict of interest.

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Table 1. Attrition rates over the three time points.

	Time 1	Time 2 (% attrition from Time 1)	Time 3 (% attrition from Time 1)
PNI group	30	25 (17)	6 (76)
TAU group	21	16 (24)	6 (63)
Control group	22	9(59)	4(56)

Table 2. Demographic characteristics of the three groups at T1.

	PNI Group	TAU Group	Control Group
<i>Gender (males)</i>	20	15	13
	18-33	18-32	18-29
<i>Age (years)</i>	(Mean = 23.90)	(Mean = 23.90)	(Mean = 22.50)
<i>Ethnicity</i>			
<i>White British</i>	27	15	n/a
<i>Asian British</i>	3	1	n/a
<i>Asian</i>	2	2	n/a
<i>Chinese</i>	1	1	n/a
<i>White European</i>	2	2	n/a
<i>Weight at baseline</i>	51-126	48-108	42.70-108
<i>range (kg)</i>	(Mean = 87.36)	(Mean = 72.944)	(Mean = 68.81)
	152-203	155-188	157-183
<i>Height range (cm)</i>	(Mean = 173.90)	(Mean = 171.158)	(Mean = 169.20)
<i>Time seen by EI</i>			
<i>Team range</i>	6-39	5-69	n/a
<i>(months)</i>	(Mean = 20.77)	(Mean = 25.16)	

Table 3. Comparison of mean Nutritional Knowledge total scores between groups at baseline (T1) and non-parametric Kruskal-Wallis Test. *Data for this outcome was missing for 9 participants in the control group who declined completion.

	N	Mean	Std. Deviation
PNI	30	19.00	5.942
TAU	21	19.62	4.031
Control	13*	20.08	3.570

Kruskall-Wallis Test			
	χ^2	df	Sig.
	.061	2	.970

Table 4. Comparison of mean Readiness to Change Eating Habits scores between groups at baseline (T1).

	N	Mean	Std. Deviation
PNI	30	9.733	2.666
TAU	21	9.548	2.472
Control	22	9.833	2.629

Table 5. Comparison of variation in Readiness to Change (T2-T1) scores between groups.

	N	Mean	Minimum	Maximum	Std. Deviation
PNI Group	25	1.750	-9.50	10.00	3.993
TAU Group	16	2.539	-4.75	9.25	4.378
Control Group	9	.1667	-2.00	4.75	2.691

Independent Samples ANOVA			
	F	df	Sig.
	.730	2	.488

Figure 1. Graph indicating the degree of negative change in readiness scores between T1 and T2 (regression), and positive change between T1 and T2 (progression), between the three groups.