

ICMJE DISCLOSURE FORM

Date: 12/29/2023

Your Name: Alexandra Wright-Hughes

Manuscript Title: Management of diarrhoea in patients with stable ulcerative colitis: multi-arm multi-stage trial of low FODMAP diet, amitriptyline, ondansetron, or loperamide (MODULATE)

Manuscript Number (if known): HTA Reference number: 17/33/03

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. "Related" means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

The author's relationships/activities/interests should be defined broadly. For example, if your manuscript pertains to the epidemiology of hypertension, you should declare all relationships with manufacturers of antihypertensive medication, even if that medication is not mentioned in the manuscript.

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| | | randomised feasibility study with a mixed-methods design. University of Manchester. | |
| | | MRC funded MILESTONE mechanistic RCT - Emotional cognitive bias modification in depression. University of Bristol. | Trial Steering Committee: Independent statistician |
| | | NIHR fellowship award: MONITOR and SPEED Trial Within a Cohort. University of Oxford. | Trial Steering Committee: Independent statistician |
| | | NIHR PHR STORM: The Standing up for Myself (STORM) psychosocial group intervention for young people and adults with intellectual disabilities: Feasibility study. University College London. | Trial Steering Committee: Independent statistician |
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| 10 | Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid | <input type="checkbox"/> None | |
| | | Statistical/trial design expert Committee member for the Yorkshire and North East Regional Advisory Committee for NIHR Research for Patient Benefit | Payment for travel where applicable only |
| | | Protocol editor for Trials | Payment made to institution |
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| 11 | Stock or stock options | <input checked="" type="checkbox"/> None | |
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| 12 | Receipt of equipment, materials, drugs, medical writing, gifts or other services | <input checked="" type="checkbox"/> None | |
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| <p>Please place an "X" next to the following statement to indicate your agreement:</p> <p><input checked="" type="checkbox"/> I certify that I have answered every question and have not altered the wording of any of the questions on this form.</p> | | | |

ICMJE DISCLOSURE FORM

Date: 11/10/2023

Your Name: Thomas Willis

Manuscript Title: Management of diarrhoea in patients with stable ulcerative colitis: multi-arm multi-stage trial of low FODMAP diet, amitriptyline, ondansetron, or loperamide (MODULATE)

Manuscript Number (if known): HTA Reference number: 17/33/03

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☒ I certify that I have answered every question and have not altered the wording of any of the questions on this form.

ICMJE DISCLOSURE FORM

Date: 11/21/2023

Your Name: Christopher Taylor

Manuscript Title: Management of diarrhoea in patients with stable ulcerative colitis: multi-arm multi-stage trial of low FODMAP diet, amitriptyline, ondansetron, or loperamide (MODULATE)

Manuscript Number (if known): HTA Reference number: 17/33/03

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ICMJE DISCLOSURE FORM

Date: 11/14/2023

Your Name: Emma Pryde

Manuscript Title: Management of diarrhoea in patients with stable ulcerative colitis: multi-arm multi-stage trial of low FODMAP diet, amitriptyline, ondansetron, or loperamide (MODULATE)

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Please place an "X" next to the following statement to indicate your agreement:

☒ I certify that I have answered every question and have not altered the wording of any of the questions on this form.

ICMJE DISCLOSURE FORM

Date: 11/15/2023

Your Name: Pei Loo Ow

Manuscript Title: Management of diarrhoea in patients with stable ulcerative colitis: multi-arm multi-stage trial of low FODMAP diet, amitriptyline, ondansetron, or loperamide (MODULATE)

Manuscript Number (if known): HTA Reference number: 17/33/03

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ICMJE DISCLOSURE FORM

Date: 11/15/2021

Your Name: Chris Probert

Manuscript Title: Management of diarrhoea in patients with stable ulcerative colitis: multi-arm multi-stage trial of low FODMAP diet, amitriptyline, ondansetron, or loperamide (MODULATE)

Manuscript Number (if known): HTA Reference number: 17/33/03

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ICMJE DISCLOSURE FORM

Date: 12/13/2023

Your Name: Delia Muir

Manuscript Title: Management of diarrhoea in patients with stable ulcerative colitis: multi-arm multi-stage trial of low FODMAP diet, amitriptyline, ondansetron, or loperamide (MODULATE)

Manuscript Number (if known): HTA Reference number: 17/33/03

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| 9 | Participation on a Data Safety Monitoring Board or Advisory Board | <input checked="" type="checkbox"/> None <table border="1"> <tr><td></td><td></td></tr> <tr><td></td><td></td></tr> <tr><td></td><td></td></tr> </table> | | | | | | | | | |
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| 11 | Stock or stock options | <input checked="" type="checkbox"/> None <table border="1" style="width: 100%; margin-top: 5px;"> <tr><td></td><td></td></tr> <tr><td></td><td></td></tr> <tr><td></td><td></td></tr> </table> | | | | | | | |
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| 12 | Receipt of equipment, materials, drugs, medical writing, gifts or other services | <input checked="" type="checkbox"/> None <table border="1" style="width: 100%; margin-top: 5px;"> <tr><td></td><td></td></tr> <tr><td></td><td></td></tr> <tr><td></td><td></td></tr> </table> | | | | | | | |
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| 13 | Other financial or non-financial interests | <input checked="" type="checkbox"/> None <table border="1" style="width: 100%; margin-top: 5px;"> <tr><td></td><td></td></tr> <tr><td></td><td></td></tr> <tr><td></td><td></td></tr> </table> | | | | | | | |
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Please place an "X" next to the following statement to indicate your agreement:

☒ I certify that I have answered every question and have not altered the wording of any of the questions on this form.

ICMJE DISCLOSURE FORM

Date: 11/11/2023

Your Name: Lauren Moreau

Manuscript Title: Management of diarrhoea in patients with stable ulcerative colitis: multi-arm multi-stage trial of low FODMAP diet, amitriptyline, ondansetron, or loperamide (MODULATE)

Manuscript Number (if known): HTA Reference number: 17/33/03

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. "Related" means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

The author's relationships/activities/interests should be defined broadly. For example, if your manuscript pertains to the epidemiology of hypertension, you should declare all relationships with manufacturers of antihypertensive medication, even if that medication is not mentioned in the manuscript.

In item #1 below, report all support for the work reported in this manuscript without time limit. For all other items, the time frame for disclosure is the past 36 months.

| | | Name all entities with whom you have this relationship or indicate none (add rows as needed) | Specifications/Comments (e.g., if payments were made to you or to your institution) | | | | | | |
|--|--|---|---|--|--|--|--|--|--|
| Time frame: Since the initial planning of the work | | | | | | | | | |
| 1 | All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) No time limit for this item. | <div style="display: flex; align-items: center;"> <input checked="" type="checkbox"/> None </div> <table border="1" style="width: 100%; margin-top: 10px;"> <tr><td style="height: 20px;"></td><td style="height: 20px;"></td></tr> <tr><td style="height: 20px;"></td><td style="height: 20px;"></td></tr> <tr><td style="height: 20px;"></td><td style="height: 20px;"></td></tr> </table> | | | | | | | |
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| Time frame: past 36 months | | | | | | | | | |
| 2 | Grants or contracts from any entity (if not indicated in item #1 above). | <div style="display: flex; align-items: center;"> <input checked="" type="checkbox"/> None </div> <table border="1" style="width: 100%; margin-top: 10px;"> <tr><td style="height: 20px;"></td><td style="height: 20px;"></td></tr> <tr><td style="height: 20px;"></td><td style="height: 20px;"></td></tr> <tr><td style="height: 20px;"></td><td style="height: 20px;"></td></tr> </table> | | | | | | | |
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| 3 | Royalties or licenses | <div style="display: flex; align-items: center;"> <input checked="" type="checkbox"/> None </div> <table border="1" style="width: 100%; margin-top: 10px;"> <tr><td style="height: 20px;"></td><td style="height: 20px;"></td></tr> <tr><td style="height: 20px;"></td><td style="height: 20px;"></td></tr> <tr><td style="height: 20px;"></td><td style="height: 20px;"></td></tr> </table> | | | | | | | |
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Please place an "X" next to the following statement to indicate your agreement:

☒ I certify that I have answered every question and have not altered the wording of any of the questions on this form.

ICMJE DISCLOSURE FORM

Date: 11/21/2023

Your Name: Yvonne McKenzie

Manuscript Title: Management of diarrhoea in patients with stable ulcerative colitis: multi-arm multi-stage trial of low FODMAP diet, amitriptyline, ondansetron, or loperamide (MODULATE)

Manuscript Number (if known): HTA Reference number: 17/33/03

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. "Related" means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

The author's relationships/activities/interests should be defined broadly. For example, if your manuscript pertains to the epidemiology of hypertension, you should declare all relationships with manufacturers of antihypertensive medication, even if that medication is not mentioned in the manuscript.

In item #1 below, report all support for the work reported in this manuscript without time limit. For all other items, the time frame for disclosure is the past 36 months.

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| Time frame: Since the initial planning of the work | | | | | | | | | |
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Please place an "X" next to the following statement to indicate your agreement:

☒ I certify that I have answered every question and have not altered the wording of any of the questions on this form.

ICMJE DISCLOSURE FORM

Date: _10/11/2023

Your Name: Nicholas Kennedy

Manuscript Title: _ Management of diarrhoea in patients with stable ulcerative colitis: multi-arm multi-stage trial of low FODMAP diet, amitriptyline, ondansetron, or loperamide (MODULATE)

Manuscript number (if known):_ HTA Reference number: 17/33/03

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. "Related" means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

The following questions apply to the author's relationships/activities/interests as they relate to the current manuscript only.

The author's relationships/activities/interests should be defined broadly. For example, if your manuscript pertains to the epidemiology of hypertension, you should declare all relationships with manufacturers of antihypertensive medication, even if that medication is not mentioned in the manuscript.

In item #1 below, report all support for the work reported in this manuscript without time limit. For all other items, the time frame for disclosure is the past 36 months.

| | | Name all entities with whom you have this relationship or indicate none (add rows as needed) | Specifications/Comments (e.g., if payments were made to you or to your institution) |
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| Time frame: Since the initial planning of the work | | | |
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| Time frame: past 36 months | | | |
| 2 | Grants or contracts from any entity (if not indicated in item #1 above). | <input type="checkbox"/> None | Payable to institution: AbbVie, Biogen, Celgene, Celltrion, Galapagos, MSD, Napp, Pfizer, Pharmacosmos, Roche, and Takeda |
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| 3 | Royalties or licenses | <input checked="" type="checkbox"/> None | |
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| 4 | Consulting fees | <input type="checkbox"/> None | Amgen, Bristol Myers Squibb, Celltrion, Falk, Galapagos, Janssen, Pfizer, Pharmacosmos, Takeda, and Tillotts, payable to self |
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| 6 | Payment for expert testimony | <input checked="" type="checkbox"/> None | |
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| 7 | Support for attending meetings and/or travel | <input type="checkbox"/> None | AbbVie, Falk, Janssen, and Pharmacosmos |
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| 8 | Patents planned, issued or pending | <input checked="" type="checkbox"/> None | |
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| 9 | Participation on a Data Safety Monitoring Board or Advisory Board | <input type="checkbox"/> None | Participation in the Data Monitoring Committee for BEACON study |
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| 10 | Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid | <input type="checkbox"/> None | Chair of British Society of Gastroenterology IBD Clinical Research Group |
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| 11 | Stock or stock options | <input checked="" type="checkbox"/> None | |
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| 12 | Receipt of equipment, materials, drugs, medical writing, gifts or other services | <input checked="" type="checkbox"/> None | |
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Please place an "X" next to the following statement to indicate your agreement:

☒ I certify that I have answered every question and have not altered the wording of any of the questions on this form.

ICMJE DISCLOSURE FORM

Date: 11/13/2023

Your Name: KAREN KEMP

Manuscript Title: Management of diarrhoea in patients with stable ulcerative colitis: multi-arm multi-stage trial of low FODMAP diet, amitriptyline, ondansetron, or loperamide (MODULATE)

Manuscript Number (if known): HTA Reference number: 17/33/03

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☒ I certify that I have answered every question and have not altered the wording of any of the questions on this form.

ICMJE DISCLOSURE FORM

Date: 11/10/2023

Your Name: Prof Lesley A Houghton

Manuscript Title: Management of diarrhoea in patients with stable ulcerative colitis: multi-arm multi-stage trial of low FODMAP diet, amitriptyline, ondansetron, or loperamide (MODULATE)

Manuscript Number (if known): HTA Reference number: 17/33/03

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ICMJE DISCLOSURE FORM

Date: 11/15/2023

Your Name: Sandra Graca

Manuscript Title: Management of diarrhoea in patients with stable ulcerative colitis: multi-arm multi-stage trial of low FODMAP diet, amitriptyline, ondansetron, or loperamide (MODULATE)

Manuscript Number (if known): HTA Reference number: 17/33/03

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ICMJE DISCLOSURE FORM

Date: 9/16/2024

Your Name: Suzanne Hartley

Manuscript Title: Management of diarrhoea in patients with stable ulcerative colitis: multi-arm multi-stage trial of low FODMAP diet, amitriptyline, ondansetron, or loperamide (MODULATE)

Manuscript Number (if known): HTA Reference number: 17/33/03

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Please place an "X" next to the following statement to indicate your agreement:

☒ I certify that I have answered every question and have not altered the wording of any of the questions on this form.

ICMJE DISCLOSURE FORM

Date: 11/20/2023

Your Name: Elspeth Guthrie

Manuscript Title: Management of diarrhoea in patients with stable ulcerative colitis: multi-arm multi-stage trial of low FODMAP diet, amitriptyline, ondansetron, or loperamide (MODULATE)

Manuscript Number (if known): HTA Reference number: 17/33/03

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. "Related" means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

The author's relationships/activities/interests should be defined broadly. For example, if your manuscript pertains to the epidemiology of hypertension, you should declare all relationships with manufacturers of antihypertensive medication, even if that medication is not mentioned in the manuscript.

In item #1 below, report all support for the work reported in this manuscript without time limit. For all other items, the time frame for disclosure is the past 36 months.

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ICMJE DISCLOSURE FORM

Date: 11/10/2023

Your Name: Alexander C. Ford

Manuscript Title: Management of diarrhoea in patients with stable ulcerative colitis: multi-arm multi-stage trial of low FODMAP diet, amitriptyline, ondansetron, or loperamide (MODULATE)

Manuscript Number (if known): HTA Reference number: 17/33/03

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ICMJE DISCLOSURE FORM

Date: 10/4/2024

Your Name: Amanda J Farrin

Manuscript Title: Management of diarrhoea in patients with stable ulcerative colitis: multi-arm multi-stage trial of low FODMAP diet, amitriptyline, ondansetron, or loperamide (MODULATE)

Manuscript Number (if known): HTA Reference number: 17/33/03

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| | | Heart Foundation, National Health and Medical Research Council, Australia. RENAL-HF: Personalising renal function monitoring and interventions in people living with heart failure NIHR-funded PGfAR | Programme Steering Committee: Independent Statistician (unpaid) | | | | | | |
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Please place an "X" next to the following statement to indicate your agreement:

☒ I certify that I have answered every question and have not altered the wording of any of the questions on this form.

ICMJE DISCLOSURE FORM

Date: Click or tap to enter a date.

Your Name: Prof Matthew Brookes

Manuscript Title: Management of diarrhoea in patients with stable ulcerative colitis: multi-arm multi-stage trial of low FODMAP diet, amitriptyline, ondansetron, or loperamide (MODULATE)

Manuscript Number (if known): HTA Reference number: 17/33/03

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. "Related" means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

The author's relationships/activities/interests should be defined broadly. For example, if your manuscript pertains to the epidemiology of hypertension, you should declare all relationships with manufacturers of antihypertensive medication, even if that medication is not mentioned in the manuscript.

In item #1 below, report all support for the work reported in this manuscript without time limit. For all other items, the time frame for disclosure is the past 36 months.

| | | Name all entities with whom you have this relationship or indicate none (add rows as needed) | Specifications/Comments (e.g., if payments were made to you or to your institution) | | | | | | |
|--|--|---|---|--|--|--|--|--|--|
| Time frame: Since the initial planning of the work | | | | | | | | | |
| 1 | All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) No time limit for this item. | <div style="display: flex; align-items: center;"> <input checked="" type="checkbox"/> None </div> <table border="1" style="width: 100%; margin-top: 10px;"> <tr><td style="height: 20px;"></td><td style="height: 20px;"></td></tr> <tr><td style="height: 20px;"></td><td style="height: 20px;"></td></tr> <tr><td style="height: 20px;"></td><td style="height: 20px;"></td></tr> </table> | | | | | | | |
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| 2 | Grants or contracts from any entity (if not indicated in item #1 above). | <div style="display: flex; align-items: center;"> <input checked="" type="checkbox"/> None </div> <table border="1" style="width: 100%; margin-top: 10px;"> <tr><td style="height: 20px;"></td><td style="height: 20px;"></td></tr> <tr><td style="height: 20px;"></td><td style="height: 20px;"></td></tr> <tr><td style="height: 20px;"></td><td style="height: 20px;"></td></tr> </table> | | | | | | | |
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| 3 | Royalties or licenses | <div style="display: flex; align-items: center;"> <input checked="" type="checkbox"/> None </div> <table border="1" style="width: 100%; margin-top: 10px;"> <tr><td style="height: 20px;"></td><td style="height: 20px;"></td></tr> <tr><td style="height: 20px;"></td><td style="height: 20px;"></td></tr> <tr><td style="height: 20px;"></td><td style="height: 20px;"></td></tr> </table> | | | | | | | |
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| 5 | Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events | <input checked="" type="checkbox"/> None <table border="1"> <tr><td></td><td></td></tr> <tr><td></td><td></td></tr> <tr><td></td><td></td></tr> </table> | | | | | | | | | |
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| 7 | Support for attending meetings and/or travel | <input checked="" type="checkbox"/> None <table border="1"> <tr><td></td><td></td></tr> <tr><td></td><td></td></tr> <tr><td></td><td></td></tr> </table> | | | | | | | | | |
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