The Gentle Years Yoga Trial

Screening Questionnaire

(Box for office use only)

GP ID: ☐☐☐ Participant ID Number: ☐☐☐☐☐

Eligibility: ☐ Y ☐ N

Enc: P ☐ M ☐ Tick if re-screening ☐

[IF COMPLETING BY TELEPHONE, SKIP THIS SECTION: If you are willing to take part in the trial then please complete this questionnaire in full and return it, using the pre-paid and addressed envelope provided.

This screening questionnaire will enable us to assess your initial eligibility to take part in the study. When we receive your response, we will contact your GP to ask them to confirm your eligibility. We will then contact you to inform you whether you are eligible or ineligible to take part in the study.
Thank you.]

[INSERT NAME] (Trial Coordinator)
The Gentle Years Yoga Trial
York Trials Unit, ARRC, Lower Ground Floor
Department of Health Sciences
The University of York, York, YO10 5DD

This study is funded by the National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme. The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

FUNDED BY NIHR | National Institute for Health Research

[IF COMPLETED BY PHONE, THE RESEARCHER WILL READ THE INSTRUCTIONS TO THE PARTICIPANT:

[IF COMPLETING BY POST, INSERT: **Please read all the instructions before completing the questionnaire.]**

The information you provide will be treated confidentially. You will not be personally identified in any report or publication resulting from this study.

Please answer ALL the questions. Some of the questions may seem unnecessary or repetitive. However we would like to reassure you that they are important to the study. Please answer all questions honestly and to the best of your ability.

Please don't deliberate too much. You may feel unsure when answering some of the questions. However, your first instinctive answer is probably the most accurate.

[IF COMPLETING BY POST, INSERT: When answering questions, use a cross rather than a tick, as if you are filling out a ballot paper. For example in the following question, if your answer to the question is yes, you should place a cross firmly in the box next to yes.

Example:

Yes ☒

No ☐

If you make a mistake then please place a single line through the original entry, and write the correct information to the side.

Please use a blue or black pen.]

[IF COMPLETING BY POST, INSERT: If you have any questions about completing this questionnaire, please contact [INSERT NAME, CONTACT DETAILS AND AVAILABILITY.]

This questionnaire is designed to assess your suitability for entry into the study. It will ask you some general questions about yourself and a series of questions about your medical conditions.

[DATED BY RESEARCHER IF COMPLETED BY TELEPHONE; ONLY INCLUDE THIS FOR COMPLETION BY POST: Please enter the date you started DD/MM/YYYY
this questionnaire (today's date)]

Section 1

In this section we would like to gather some general details about you.

1. What is your **date of birth**?
   DD/MM/YYYY

Please answer the following questions [IF BY POST: by putting a cross in the appropriate box]. Please only [IF BY PHONE: choose] [IF BY POST: cross] one [IF BY PHONE: option] [IF BY POST: box] per question.

2. **Which of these best describes your residential status?**
   - ☐ Living in a Care Home
   - ☐ Living alone in the Community
   - ☐ Living with one or more other people in the Community
   - ☐ Living in sheltered housing with support

3. **During the past six months, have you taken part in yoga classes in person or online twice a month or more?**

   YES ☐ NO ☐

4. **The yoga classes and questionnaires will only be available in English. Will this be an obstacle to your participation?**

   YES ☐ NO ☐

5. **Are you currently involved in any other clinical trials?**
[INSERT IF BY POST: (If 'YES', we may need to telephone you to obtain further details)]

YES ☐ NO ☐

As explained in the **Participant Information Sheet** and **Trial Diagram**, a computer programme will be used to randomly choose which type of participant you will be. You have a 50:50 chance of being either a:

- Usual Care participant (control group)
- Yoga participant (intervention group)

[INSERT FOR 'ONLINE INTERVENTION DELIVERY' **OR** 'FACE-TO-FACE AND ONLINE BLENDED INTERVENTION DELIVERY':

For participants allocated to the yoga group, the yoga classes **[**INSERT FOR 'ONLINE INTERVENTION DELIVERY': will be] [INSERT FOR 'FACE-TO-FACE AND ONLINE BLENDED INTERVENTION DELIVERY': may be] delivered online via video conferencing (e.g Zoom). Prior to the first class, the yoga teacher will contact you individually to go over how you would access the online classes from home using your computer device. In order to participate in the online classes, you will need to have access to a few things at home. Please indicate by choosing 'yes' or 'no' whether or not you have access to the following at home:

6. **Do you have regular access to a reliable internet connection?**

YES ☐ NO ☐

7. **Are you familiar with the internet and able to use it?**

YES ☐ NO ☐

8. **Do you have a suitable electronic device with which you will be able to access the yoga classes (suitable devices are those**

with a camera, speakers, a microphone, and a tablet-size screen or larger)?

YES ☐ NO ☐

9. **Do you have sufficient space at home to practice yoga (a space of 6 feet by 9 feet, where you can place your device approximately 8 feet in front of your chair)?**

YES ☐ NO ☐

10. **Do you have a sturdy chair for use in the classes?**

YES ☐ NO ☐

Section 2

In this section we would like information of any **current** long-term medical conditions you have. Below is a list of common conditions. For each, please tell us whether you have **been diagnosed with this** condition by a healthcare professional e.g. doctor, specialist, nurse, etc.

[IF COMPLETING BY POST INSERT: When you see a condition you currently have or are being treated for, please place a cross in the corresponding 'YES' box. If you do not have a condition please cross the corresponding 'NO' box. For each condition you do have, please tell us how much it limits your daily activities from 1 (NOT AT ALL) to 5 (A LOT) by putting a cross in one of the corresponding five boxes.]

[IF COMPLETING BY TELEPHONE: THE RESEARCHER WILL READ THE OPTIONS AND COMPLETE THE FORM ACCORDINGLY]

Medical Condition	Do you have this condition? YES	NO	I DO have this condition and it limits my daily activities NOT AT ALL ……..LOT 1	2	3	4	5
Osteoarthritis of the shoulder, hip or knee	☐	☐	☐	☐	☐	☐	☐

("regular" arthritis, not rheumatoid arthritis) Please see Footnote 1 below		
Rheumatoid arthritis of the shoulder, hip or knee Please see Footnote 1 below	☐ ☐	☐ ☐ ☐ ☐ ☐ 1 2 3 4 5
Asthma	☐ ☐	☐ ☐ ☐ ☐ ☐ 1 2 3 4 5
Chronic obstructive pulmonary disease (COPD) including chronic bronchitis or emphysema	☐ ☐	☐ ☐ ☐ ☐ ☐ 1 2 3 4 5
Atrial fibrillation	☐ ☐	☐ ☐ ☐ ☐ ☐ 1 2 3 4 5
Cancer during the last 5 years	☐ ☐	☐ ☐ ☐ ☐ ☐ 1 2 3 4 5
Chronic kidney disease	☐ ☐	☐ ☐ ☐ ☐ ☐ 1 2 3 4 5

Footnote 1: If you have received shoulder, hip or knee reconstruction or replacement for osteoarthritis or rheumatoid arthritis, please tick 'yes' to osteoarthritis or rheumatoid arthritis as appropriate in the above table.

Medical Condition	**Do you have this condition?** **YES** **NO**	**I DO have this condition and it limits my daily activities** **NOT AT ALL ……..A LOT**
Coronary heart disease including angina (chest pain from heart problem) or history of heart attack, bypass surgery or angioplasty	☐ ☐	☐ ☐ ☐ ☐ ☐ 1 2 3 4 5
Hypertension (high blood pressure)	☐ ☐	☐ ☐ ☐ ☐ ☐ 1 2 3 4 5
Heart failure	☐ ☐	☐ ☐ ☐ ☐ ☐ 1 2 3 4 5
Peripheral arterial disease (poor blood circulation in your legs)	☐ ☐	☐ ☐ ☐ ☐ ☐ 1 2 3 4 5
Dementia	☐ ☐	☐ ☐ ☐ ☐ ☐ 1 2 3 4 5

Depression	☐	☐	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Anxiety	☐	☐	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Diabetes	☐	☐	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Epilepsy	☐	☐	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Fibromyalgia	☐	☐	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Multiple sclerosis	☐	☐	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Osteoporosis or osteopenia (thinning of the bones)	☐	☐	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Parkinson's disease	☐	☐	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Deafness or severe problem with hearing	☐	☐	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Medical Condition	**Do you have this condition?** **YES**	**NO**	**I DO have this condition and it limits my daily activities** **NOT AT ALL**				**A LOT**
Blindness or severe problem with vision (e.g. macular degeneration, glaucoma)	☐	☐	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Stroke during the last 5 years	☐	☐	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Thyroid disorder	☐	☐	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Chronic back pain or sciatica	☐	☐	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Stomach problem such as an ulcer or gastritis or reflux	☐	☐	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Bowel problems (e.g. IBS, diverticulitis, or inflammatory bowel disease)	☐	☐	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Overweight or obesity	☐	☐	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Severe mental health problems (e.g. schizophrenia, bipolar affective disorder or other psychotic illness)	☐ ☐	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Learning Disability	☐ ☐	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Do you have any other long-term medical conditions that were not mentioned above? If so, please list them here:		**I DO have this condition and it limits my daily activities** **NOT A AT ALL .....LOT**
		☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
		☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
		☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

[INSERT PARTICIPANT ID]

Section 3

In this section we would like to know about your availability for the yoga classes. Please note, you will only receive yoga classes if you are randomly chosen by the computer programme to be a yoga participant. [IF COMPLETING BY POST INSERT: The following table shows a list of yoga courses available [INSERT FOR 'FACE-TO-FACE INTERVENTION DELIVERY' or 'FACE-TO-FACE AND ONLINE BLENDED INTERVENTION DELIVERY': in different regions around the UK] and relevant details such as the start date, day and time of classes.] [IF COMPLETING BY TELEPHONE THE RESEARCHER WILL READ FROM THE APPROPRIATE TABLE AND COMPLETE IT ACCORDINGLY]

Please:

[INSERT THE FOLLOWING INSTRUCTIONS AND TABLE FOR 'FACE-TO-FACE INTERVENTION DELIVERY':

[IF COMPLETING BY POST THE PARTICIPANT WILL FOLLOW THE INSTRUCTIONS. IF COMPLETING BY TELEPHONE, THE RESEARCHER READ THE OPTIONS AND COMPLETE THE FORM ACCORDINGLY.]

[INSTRUCTIONS FOR POSTAL COMPLETION:

1. Choose your region down the left hand column
2. If there is more than one class provided in your region please look at each option carefully and decide whether you would be able to attend either class. Indicate your availability by marking a cross in the 'yes' or 'no' box next to the day and time of each venue to indicate whether you can attend. **Please note that you can indicate 'yes' for more than one class.**
3. If there is only one class available in your area please determine whether you would likely be able to attend on this day and time each week and indicate your response by marking a cross in the 'yes' or 'no' box next to the day and time. Apologies if only one option is provided, this is based on the availability of the yoga teachers.]

Region	Venue	Start date	Day	Time	Response	Office use
XXXXXXXX	XXXXXXXX	Xxxxxxx	XXXXXXXXX	XXXXXXXX	Yes ☐ No ☐ [IF COMPLETING BY TELEPHONE, INSERT: Not asked] ☐	[insert site ID]
XXXXXXXX	XXXXXXXX	Xxxxxxx	XXXXXXXXX	XXXXXXXX	Yes ☐ No ☐ [IF COMPLETING BY TELEPHONE, INSERT: Not asked] ☐	[insert site ID]

[INSERT THE FOLLOWING INSTRUCTIONS AND TABLE FOR 'FACE-TO-FACE AND ONLINE BLENDED INTERVENTION DELIVERY, OR WHERE OFFERING BOTH 'FACE-TO-FACE AND ONLINE BLENDED INTERVENTION DELIVERY' AND 'ONLINE INTERVENTION DELIVERY'

[IF COMPLETING BY POST THE PARTICIPANT WILL FOLLOW THE INSTRUCTIONS. IF COMPLETING BY TELEPHONE, THE RESEARCHER READ THE OPTIONS AND COMPLETE THE FORM ACCORDINGLY.]

[INSTRUCTIONS FOR POSTAL COMPLETION:

Please see below the details of each of the yoga classes we will be running. The classes detailed below will be delivered either face-to-face in the community, via online video conferencing, or a mixture of both face-to-face and online classes.

Please note, if face-to-face classes cannot go ahead in your location due to COVID-19 guidance, the classes will run online on the same day and time. This decision will depend on government COVID-19 guidelines and will be confirmed nearer the time of the classes.

Please look at each option carefully and confirm whether or not you would be able to attend either class if it were to take place online or at the venue. **Please note that you can indicate 'yes' for more than one class.]**

Mode of delivery	**Region**	**Venue**	**Start date**	**Day**	**Time**	**Response**	**Office use**
[INSERT 'Online', OR 'Face-to-face']	[IF ONLINE ONLY, INSERT: 'n/a' [IF FACE TO FACE, INSERT: region]	[IF ONLINE ONLY, INSERT: 'n/a' [IF FACE TO FACE,	Xxxxxxx	XXXXX XXXX	XXXXX XXX	Yes – if face-to-face classes ☐ Yes – if online classes ☐ No ☐	[insert site ID]

		INSERT: venue]				[IF COMPLETING BY TELEPHONE, INSERT: Not asked ☐]	
[INSERT 'ONLINE', OR 'Face-to-face']	[IF ONLINE ONLY, INSERT: 'n/a' [IF FACE TO FACE, INSERT: region]	[IF ONLINE ONLY, INSERT: 'n/a' [IF FACE TO FACE, INSERT: venue]	Xxxxxxx	XXXXX XXXX	XXXXX XXX	Yes – if face-to-face classes ☐ Yes – if online classes ☐] No ☐ [IF COMPLETING BY TELEPHONE, INSERT: Not asked ☐]	[insert site ID]

]

[INSERT THE FOLLOWING INSTRUCTIONS AND TABLE FOR 'ONLINE INTERVENTION DELIVERY':

[IF COMPLETING BY POST THE PARTICIPANT WILL FOLLOW THE INSTRUCTIONS. IF COMPLETING BY TELEPHONE, THE RESEARCHER WILL READ THE OPTIONS AND COMPLETE THE FORM ACCORDINGLY.]

[INSTRUCTIONS FOR POSTAL COMPLETION:

Please look at each option carefully and decide whether you would be able to attend either class. Indicate your availability by choosing the 'yes' or 'no' box next to each day and time to indicate whether you can attend. **Please note that you can indicate 'yes' for more than one class.]**

Start Date	**Day**	**Time**	**Response**	**Office use**

Xxxxxxxxx	XXXXXXXXX	XXXXXXXX	Yes ☐ No ☐ [IF COMPLETING BY TELEPHONE, INSERT: Not asked ☐]	[insert site ID]
Xxxxxxxxx	XXXXXXXXX	XXXXXXXX	Yes ☐ No ☐ [IF COMPLETING BY TELEPHONE, INSERT: Not asked ☐]	[insert site ID]

]

If you are randomised to the yoga group, will you be able to attend at least 9 of the 12 yoga classes?

Yes ☐

No ☐

Can you please indicate below what level of support you had completing this questionnaire by putting a cross in the box next to the most appropriate statement.

I had help completing this questionnaire ☐

I completed this questionnaire on my own ☐

Thank you for completing the questionnaire.

[IF COMPLETED BY POST INSERT: **Please send it to the study team by putting it in the large pre-paid and addressed envelope provided**

and posting as normal.
No postage stamps are required.]

The Gentle Years Yoga Trial
Baseline Questionnaire

(Office use only)

Participant ID Number: | | | | | |

Date Sent: | | / | | / | | Tick if re-screen | |
day / month / year

[IF COMPLETING BY TELEPHONE, SKIP THIS SECTION:]Thank you for your interest in this study.

If you are willing to take part in the Gentle Years Yoga Trial then please complete this questionnaire in full and return it, using the pre-paid addressed envelope provided.

When we receive your completed questionnaire, we will write to you within approximately four weeks to let you know whether you have been entered in the study and, if so, which group you have been randomly allocated to.

If you have any questions about completing this questionnaire, please contact [INSERT TRIAL COORDINATOR NAME, NUMBER AND EMAIL].

The Gentle Years Yoga Trial
York Trials Unit, ARRC, Lower Ground Floor
Department of Health Sciences
The University of York
York, YO10 5DD

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FUNDED BY NIHR | National Institute for Health Research

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Please answer ALL the questions. Some of the questions may seem unnecessary or repetitive. However, we would like to reassure you that they are important to the study. Please answer all questions honestly and to the best of your ability.

Please don't deliberate too much. You may feel unsure when answering some of the questions. However, your first instinctive answer is probably the most accurate.

[IF COMPLETING BY POST, INSERT: If you are asked to write in an answer, please print clearly.
Example:

Number of visits	0 8

If you are asked show your response using a tick, please place a tick in the box as clearly as possible.
Example: ☑

Some questions require you to mark a cross, which enables us to judge the severity of a particular problem.

Do not worry if you make a mistake. Please place a single line through the original entry and write the correct information to the side.

Please use a blue or black pen.]

[DATED BY RESEARCHER IF COMPLETED BY TELEPHONE; ONLY INCLUDE THIS FOR COMPLETION BY POST:
Please enter the date you started this questionnaire (**today's** date)]

DD MM YYYY

Section 1

The following questions ask for general background information about you.

1. **What is your gender?** ☐ Male ☐ Female ☐ Prefer not to say
   (Please tick one box only)

2. **What is your ethnicity?**
   (Please tick one box only)

White British ☐	White Irish ☐	White Other ☐	Black African ☐	Black Caribbean ☐	Black Other ☐
Asian Indian ☐	Asian Pakistani ☐	Asian Bangladeshi ☐	Asian Other ☐	White and Black Caribbean ☐	White and Black African ☐
White and Asian ☐	Other mixed background ☐	Chinese ☐	Other, please state: ☐ _____		

3. **Which of the following best describes your main activity?**
   (Please tick one box only)

   ☐ Employed

   ☐ Retired

   ☐ Other _____

4. **Do you smoke?**
   (Please tick one box only)

   ☐ Yes

   ☐ No, I have never smoked

☐ No, but I used to smoke

Section 2

The following set of questions is about your general health.

Under each heading, please tick the ONE box that best describes your health TODAY.

1. MOBILITY

I have no problems in walking about ☐
I have slight problems in walking about ☐
I have moderate problems in walking about ☐
I have severe problems in walking about ☐
I am unable to walk about ☐

2. SELF-CARE

I have no problems washing or dressing myself ☐
I have slight problems washing or dressing myself ☐
I have moderate problems washing or dressing myself ☐
I have severe problems washing or dressing myself ☐
I am unable to wash or dress myself ☐

3. **USUAL ACTIVITIES** (e.g. work, study, housework, family or leisure activities)

I have no problems doing my usual activities ☐
I have slight problems doing my usual activities ☐
I have moderate problems doing my usual activities ☐
I have severe problems doing my usual activities ☐
I am unable to do my usual activities ☐

4. PAIN/DISCOMFORT

I have no pain or discomfort ☐
I have slight pain or discomfort ☐
I have moderate pain or discomfort ☐
I have severe pain or discomfort ☐
I have extreme pain or discomfort ☐

5. ANXIETY/DEPRESSION

I am not anxious or depressed ☐
I am slightly anxious or depressed ☐
I am moderately anxious or depressed ☐
I am severely anxious or depressed ☐
I am extremely anxious or depressed ☐

We would like to know how good or bad your health is TODAY.

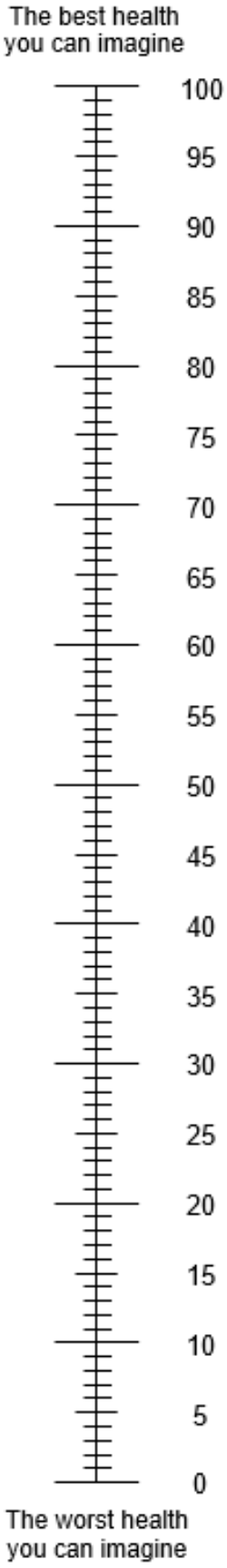
This scale is numbered from 0 to 100.

100 means the best health you can imagine.
0 means the worst health you can imagine.

Mark an X on the scale to indicate how your health is TODAY.

Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY = ☐



Section 3

Please answer the following sets of questions by placing a tick in the box that best describes your answer.

Over the last 2 weeks, how often have you been bothered by any of the following problems? *(Use ☑ to indicate your answer)*	**Not at all**	**Several days**	**More than half the days**	**Nearly every day**
Little interest or pleasure in doing things	☐ 0	☐ 1	☐ 2	☐ 3
Feeling down, depressed or hopeless	☐ 0	☐ 1	☐ 2	☐ 3
Trouble falling or staying asleep, or sleeping too much	☐ 0	☐ 1	☐ 2	☐ 3
Feeling tired or having little energy	☐ 0	☐ 1	☐ 2	☐ 3
Poor appetite or overeating	☐ 0	☐ 1	☐ 2	☐ 3
Feeling bad about yourself, or that you are a failure, or have let yourself or your family down	☐ 0	☐ 1	☐ 2	☐ 3
Trouble concentrating on things, such as reading the newspaper or watching television	☐ 0	☐ 1	☐ 2	☐ 3
Moving or speaking so slowly that other people could have noticed. Or the opposite – being so fidgety or restless that you have been moving around a lot more than usual	☐ 0	☐ 1	☐ 2	☐ 3

Over the <u>last 2 weeks</u>, how often have you been bothered by the following problems? *(Use ☑ to indicate your answer)*	**Not at all**	**Several days**	**More than half the days**	**Nearly every day**
Feeling nervous, anxious or on edge	☐ 0	☐ 1	☐ 2	☐ 3
Not being able to stop or control worrying	☐ 0	☐ 1	☐ 2	☐ 3
Worrying too much about different things	☐ 0	☐ 1	☐ 2	☐ 3
Trouble relaxing	☐ 0	☐ 1	☐ 2	☐ 3
Being so restless that it is hard to sit still	☐ 0	☐ 1	☐ 2	☐ 3
Becoming easily annoyed or irritable	☐ 0	☐ 1	☐ 2	☐ 3
Feeling afraid as if something awful might happen	☐ 0	☐ 1	☐ 2	☐ 3

Please respond to each question or statement by ticking one box per row.

Physical Function	Without any difficulty	With a little difficulty	With some difficulty	With much difficulty	Unable to do
Are you able to do chores such as vacuuming or yard work?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Are you able to go up and down stairs at a normal pace?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Are you able to go for a walk of at least 15 minutes?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Are you able to run errands and shop?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Anxiety **In the past 7 days…**	Never	Rarely	Sometimes	Often	Always
I felt fearful	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
I found it hard to focus on anything other than my anxiety	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
My worries overwhelmed me	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
I felt uneasy	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Depression **In the past 7 days…**	Never	Rarely	Sometimes	Often	Always
I felt worthless	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
I felt helpless	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
I felt depressed	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
I felt hopeless	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Fatigue **During the past 7 days…**	Not at all	A little bit	Somewhat	Quite a bit	Very much
I feel fatigued	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
I have trouble starting things because I am tired	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
How run-down did you feel on average?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
How fatigued were you on average?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Sleep Disturbance **In the past 7 days…**	Very poor	Poor	Fair	Good	Very good
My sleep quality was	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
In the past 7 days…	Not at all	A little bit	Somewhat	Quite a bit	Very much
My sleep was refreshing	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
I had a problem with my sleep	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
I had difficulty falling asleep	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Ability to Participate in Social Roles and Activities	Never	Rarely	Sometimes	Usually	Always
I have trouble doing all of my regular leisure activities with others	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
I have trouble doing all of the family activities that I want to do	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
I have trouble doing all of my usual work (include work at home)	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
I have trouble doing all of the activities with friends that I want to do	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

Pain Interference **In the past 7 days…**	Not at all	A little bit	Somewhat	Quite a bit	Very much
How much did pain interfere with your day to day activities?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
How much did pain interfere with work around the home?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
How much did pain interfere with your ability to participate in social activities?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
How much did pain interfere with your household chores?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Pain Intensity **In the past 7 days…**					
How would you rate your pain on average?	☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ 0 1 2 3 4 5 6 7 8 9 10 No pain … Worst pain imaginable				

The next questions are about how you feel about different aspects of your life. For each one, tell me how often you feel that way.
(Tick one box for each question).

	Hardly ever or never	**Some of the time**	**Often**
How often do you feel that you lack companionship?	☐	☐	☐
How often do you feel left out?	☐	☐	☐
How often do you feel isolated from others?	☐	☐	☐

How often do you feel lonely?
(Please tick one box only)

☐	☐	☐	☐	☐
Often or Always	Some of the time	Occasionally	Hardly ever	Never

The next question asks about any falls you have had.
For the sake of this study we define a fall as “an unexpected event in which you come to rest on the ground, floor or lower level".

1. **Have you fallen in the past <u>3 months</u>?** ☐ Yes ☐ No
   (Please tick one box only)

1a. **If yes, how many falls did you have in the past 3 months?**

☐☐ Falls

<u>Section 4</u>

This section is about the health care you have received **in the last 3 months**.

<u>Care from the NHS NOT in the hospital</u>

In the **past 3 months**, have you had any contact with the following health professionals in the <u>community</u>? Please tick yes OR no for each service. If “**Yes**”, please indicate how often you had contact with them.

Health Professional	Definition	Contact with them?	Number of Visits (If none enter “00”)
GP visit at practice	You saw a GP at the practice	☐ Yes ☐ No	☐☐
GP visit at home	A GP visited you in your home	☐ Yes ☐ No	☐☐
GP consultation over the phone	A GP spoke to you over the phone	☐ Yes ☐ No	☐☐
Nurse visit at practice	A nurse who works at GP practice who saw you in the GP practice	☐ Yes ☐ No	☐☐

Nurse visit at home	A nurse who works at GP practice who visited you at home	☐ Yes ☐ No	☐☐
Nurse consultation over phone	A nurse who works at GP practice who spoke to you over the phone	☐ Yes ☐ No	☐☐
District nurse visit at practice	A nurse who works in the community who saw you at GP practice	☐ Yes ☐ No	☐☐
District nurse visit at home	A nurse who works in the community who visited you at home	☐ Yes ☐ No	☐☐
District nurse consultation over phone	A nurse who works in the community who spoke to you over the phone	☐ Yes ☐ No	☐☐
Physiotherapist	A physiotherapist who works in the community who you saw at their practice, your home, or spoke to you over the phone	☐ Yes ☐ No	☐☐
Mental health services (e.g. counselling)	A mental health service professional who works in the community who you saw at their practice, your home, or spoke to you over the phone	☐ Yes ☐ No	☐☐

Care from the NHS IN the hospital

In the **past 3 months**, have you visited a NHS hospital (not private hospital) for any of the reasons below? Please tick yes OR no for each service. If "**YES**", please indicate how often for each type of visit. If you have stayed overnight, please state the total number of nights in the final column.

Hospital Visits	Definition	Had a visit?	Number of visits (If none enter "00")	Total number of nights stayed over
Physiotherapist	Appointment with a physiotherapist at the hospital	☐ Yes ☐ No	☐☐	

Mental health service	Appointment with mental health services at the hospital	☐ Yes ☐ No	☐☐	
Other out-patient appointments	Any other specialist or service in a hospital that did not require you to stay overnight (e.g., blood tests, x-rays, scans, having plaster casts fitted, occupational therapy, and podiatry).	☐ Yes ☐ No	☐☐	
Day case appointment	A planned admission to hospital, where you were given a bed but were not required to stay overnight (e.g., some cancer treatments/chemotherapy, endoscopy, colonoscopy, invasive x-rays/scan procedures)	☐ Yes ☐ No	☐☐	
Accident and Emergency visit that did not require a stay in hospital	Attended A&E, but you were not required to stay overnight	☐ Yes ☐ No	☐☐	
Planned In-patient stay in NHS hospital (not via A&E)	A stay in hospital overnight that was scheduled in advance, because it did not require a medical emergency. **In case of multiple stays** (e.g. you had a first in-patient stay of 2 nights, and a second in-patient stay of 1 night) **please report as follows:** *Number of visits: 2* *Total number of nights: 3*	☐ Yes ☐ No	☐☐	☐☐
Accident & Emergency visit **that required a stay in hospital**	Attended A&E, and you were required to stay in hospital overnight. **In case of multiple A&E visits** (e.g. first A&E visit requiring 1 night, and a second A&E visit requiring	☐ Yes ☐ No	☐☐	☐☐

	1 night) **please report as follows**: *Number of visits: 2* *Total number of nights: 2*			

Private Treatments

We would like you tell us about any additional medical treatment you have received, which you paid for (e.g. personal cost or private insurance health care).

In the **past 3 months**, have you had any contact with the following health professionals? If "**Yes**", please indicate how often you had contact with them.

Health Professional	Contact with them?	Number of Visits
Seen Private GP	☐ Yes ☐ No	☐☐
Seen a Private physiotherapist	☐ Yes ☐ No	☐☐
Seen a Private specialist for a mental health service	☐ Yes ☐ No	☐☐

Section 5

This section asks about your expectations and preferences concerning the healthcare being offered. Your responses in this section will NOT influence your entry to the study, or the group you are eventually allocated to.

1. How effective do you think that usual care would be in improving your quality of life? (Please place a tick in one box only)

Very ineffective	Fairly ineffective	Can't decide	Fairly effective	Very effective

☐ ☐ ☐ ☐ ☐

2. How effective do you think the Gentle Years Yoga programme would be in improving your quality of life? (Please place a tick in one box only)

Very ineffective	Fairly ineffective	Can't decide	Fairly effective	Very effective
☐	☐	☐	☐	☐

3. Given the choice, which study group would you prefer to be in? (Please place a tick in one box only)

☐ Yoga + usual care

☐ Usual Care

☐ No Preference

4. Please indicate below what level of support you had completing this questionnaire by putting a tick in the box of the most appropriate statement below.

☐ I had help completing this questionnaire

☐ I completed this questionnaire on my own

Thank you for completing this questionnaire, please **return it in the pre-paid envelope** provided.

Once we receive it, we will write to you to let you know whether you have been entered in the study and, if so, which group you have been randomly allocated to. You will be informed in approximately four weeks via a letter to your home address.

[GP HEADED PAPER / OR STUDY HEADED – DEPENDING ON PREFERENCE OF THE SITE / METHOD OF RECRUITMENT]

Dear [Patient] / [INSERT PATIENT'S TITLE AND NAME]

Invitation to take part in a research study

[INSERT IF RECRUITMENT IS FROM CONSENT TO BE CONTACTED BY YTU: As you have previously taken part in a study run by York Trials Unit and through this consented to being approached about other studies, we are]

[INSERT IF RECRUITMENT IS IN RESPONSE TO MEDIA ADVERTS Thank you for responding to one of our recent media adverts. Following your contact, we are]

[INSERT IF FROM GP MAIL OUT: Your GP Practice is]

[INSERT IF FROM YTU DUE TO RESCREEN OF PREVIOUS GP MAILOUT: We are]

inviting you to take part in a research project being run by the Universities of Northumbria and York called The Gentle Years Yoga Trial.

This is a research study aiming to establish the effects of a specially-designed yoga programme on the quality of life of people who have more than one long-term health condition. The yoga programme has been designed for older adults and is suitable for many people including those who have not done yoga before or who are not used to exercising, perhaps because they feel unable to do so or are worried about exercising because of their health conditions.

You do not have to take part, but before you decide it is important for you to understand why the project is being done and exactly what it will involve. Please take time to carefully read the 'Participant Information Sheet' and 'Trial Diagram' enclosed, and feel free to discuss it with your family/friends.

If there is anything that is not clear, or if you would like more information, please contact the study team on [INSERT CONTACT DETAILS].

If you would like to take part

[FOR ONLINE/TELEPHONE COMPLETION, INSERT:

1. Please go to the following web link and follow the instructions given there to complete the electronic 'Participant Consent Form': [Insert web link]
2. When you have completed the consent form and we have received your contact details, a member of the study team will be in touch with you by telephone to determine whether or not you are eligible to take part in the study.]

[FOR FULLY POSTAL COMPLETION, INSERT:

1. Please complete the enclosed 'Participant Consent Form' by initialling, ticking, or crossing each box and then turning over the page of the consent form and signing at the bottom.
2. Return the 'Participant Consent Form' in the small pre-paid and addressed envelope provided.
3. Please complete the 'Screening Questionnaire' enclosed and return this separately in the large prepaid and addressed envelope provided. The Screening Questionnaire will enable us to assess your eligibility for taking part in the study.
4. [REMOVE THIS SECTION IF RECRUITED FROM GP MAIL-OUT: Next, fill in the 'GP Details Form' and also add this to the small pre-paid envelope with your consent form.

We will be in touch with you once we receive both your completed Participant Consent Form and Screening Questionnaire.]

[FOR COMBINED POSTAL CONSENT AND ONLINE/TELEPHONE SCREENING INSERT:

1. Please complete the enclosed 'Participant Consent Form' by initialling, ticking, or crossing each box and then turning over the page of the consent form and signing at the bottom.

2. [REMOVE THIS SECTION IF RECRUITED FROM GP MAIL-OUT: Next, fill in the 'GP Details Form' and also add this to the small pre-paid envelope with your consent form.]
3. Return the 'Participant Consent Form' in the small pre-paid and addressed envelope provided.
4. When you have completed and returned the consent form and we have received your contact details, a member of the study team will be in touch with you by telephone to determine whether or not you are eligible to take part in the study.

If you choose not to take part in the main study

There will be no change to your usual care and the study team will have no access to your details. However, you can choose to take part in an interview where the reasons why you have declined would be discussed. If you opt to take part in the interview only, please just [FOR ELECTRONIC COMPLETION INSERT: go to the electronic Participant Consent Form found at the weblink provided in step 1 above, and initial] [FOR POSTAL OR COMBINED POSTAL CONSENT AND ONLINE/TELEPHONE SCREENING COMPLETION INSERT: initial, tick or cross] the box for statement number [INSERT NO] on the consent form. Then [FOR ELECTRONIC COMPLETION INSERT: enter instructions for form submission] [FOR POSTAL OR COMBINED POSTAL CONSENT AND ONLINE/TELEPHONE SCREENING COMPLETION INSERT : fill in your details and sign at the bottom. Send this back to us in the small prepaid and addressed envelope]. A member of the study team will then be in touch if you are selected for an interview.

Please note, only one person per household can be involved in the study. This is to avoid any complications which could arise if two or more people from the same household were put into different study groups.

[SWAT STUDY DETAILS TO BE INSERTED IF RANDOMISED TO RECEIVE £5 WITH INVITATION: Please find enclosed a complimentary £5 AND/OR pen given as a thank you for considering taking part. If you choose not to take part you can still keep this.]

Yours sincerely

[INSERT GP NAME OR MEMBER OF THE STUDY TEAM]

[FUNDING LOGO TO BE ADDED/REMOVED AS REQUIRED BY GP PRACTICE]

The Gentle Years Yoga Trial
A UK study of yoga for older adults with long-term health conditions

Participant Information Sheet

We are inviting you to take part in our research study.

Before you decide if you want to take part, it is important for you to understand why this research is being done, and what taking part will involve.

Please take time to read this information sheet and the Trial Diagram provided, and to discuss the information with anyone you wish, such as a friend, relative or your GP before making a final decision.

If you would prefer to listen to this information sheet, please visit our website at https://www.york.ac.uk/healthsciences/research/trials/research/trials/gyy-trial/ and scroll to the sub-heading 'Participant Information Sheet Audio Recording' near the bottom of the webpage.

1. What is the study about?

Our study team wants to find out the effect of offering a 12-week yoga programme on the quality of life of people aged 65 years and older who have more than one long-term health condition. We are aiming to recruit over 550 participants from different parts of England, Wales and Scotland.

A long-term health condition could be any condition lasting more than three months. Long-term health conditions affect everyone differently, and while some people may feel in good health, other people may need support from healthcare services to manage their condition.

There is little guidance on the best way to support people with more than one long-term health condition, but we know that yoga is a popular activity. There are many different types of yoga. Our study is interested in Gentle Years Yoga, which was developed specifically for older adults. In 2016, we ran a small study of Gentle Years Yoga, and the results suggested that yoga may help to improve physical functioning and quality of life in older adults.

2. Who is organising and funding the study?

This study is funded by the NHS 'National Institute for Health Research' Health Technology Assessment programme, and is sponsored by Northumbria University. The trial is managed by our study team based across Northumbria University and the York Trials Unit at the University of York, led by Dr Garry Tew. GP practices are supporting us to recruit our study participants.

3. What is Gentle Years Yoga?

Gentle Years Yoga was developed in 2009 by Yorkshire Yoga to meet the needs of older adults with age-related long-term health conditions. This form of yoga is suitable for people aged 65 years and over, including those who have not tried yoga before, those who have not exercised for a long time, or those who are worried about exercising because of their health conditions.

Gentle Years Yoga classes are mostly chair-based, and typically involve gentle stretching and strengthening movements, breathing practices, and relaxation. Everyone works slowly and at their own level. There is also social time at the end of class to chat to other participants.

4. Why am I being asked to take part in this research?

Our study is recruiting adults aged 65 years and older with more than one long-term health condition, including those who do not currently feel their health condition causes them any issues. We are interested in people with a wide range of health conditions.

You are being invited because your GP has indicated that you might be eligible for our study. You will complete a 'Screening Questionnaire' at the start of the study to help us to further determine your eligibility.

5. Do I have to take part?

No, you do not have to take part in this trial. If you do decide to take part you may also change your mind and withdraw from the trial at any time, without giving a reason, by contacting a member of the study team. Your decision will not affect any medical care you currently receive, or your future care.

If you do not want to take part in this study, you do not have to do anything. We do not have access to your contact information (this is held by your GP practice), unless you have provided this to us directly. If you do not respond to this invitation we are unable to contact you further, and will assume that you do not wish to participate in the study.

6. How do I take part?

[INSERT IF POSTAL CONSENT, SCREENING AND BASELINE:

If you are interested in joining our study, please complete the 'Consent Form' and 'Screening Questionnaire' included with this invitation pack, and return these to us as soon as possible using the two pre-paid envelopes enclosed (no stamp required). Please post the 'Screening Questionnaire' in the larger pre-paid envelope and the 'Consent Form' in the smaller pre-paid envelope, to keep your health information separate from your contact details.

When our study team at the University of York receives your forms they will check them to see if, at this stage, you are eligible for our study. Next, we will be in touch with your GP to confirm that there are no health concerns with you joining the study. If you are not eligible, we will send you a letter to let you know. If you are eligible, we will send you a 'Baseline Questionnaire' to complete and return, again using a pre-paid envelope. This questionnaire will collect study data about your medical history, your physical, mental, and social wellbeing, and the healthcare services you currently use. Once we receive this completed questionnaire, you will be enrolled in the study, and assigned to one of two groups.]

[INSERT IF ONLINE CONSENT AND TELEPHONE SCREENING AND BASELINE:

If you are interested in joining our study, please complete the 'Consent Form' by visiting [INSERT WEBLINK] as soon as possible.

When our study team at the University of York receives your 'Consent Form', we will be in touch with you to complete a 'Screening Questionnaire' over the telephone. Your answers to the 'Screening Questionnaire' will determine whether or not you are eligible to take part. If you are eligible, we will then ask you to complete a 'Baseline Questionnaire' whilst you are on the telephone with us. This questionnaire will collect study data about your medical history, your physical, mental, and social wellbeing, and the healthcare services you currently use. Next, we will be in touch with your GP to confirm that there are no health concerns with

you joining the study. If there are health concerns, we will send you a letter to let you know that we are unable to enrol you in the study. If there are no health concerns, you will be enrolled in the study, and assigned to one of two groups.]

[INSERT IF POSTAL CONSENT AND TELEPHONE SCREENING AND BASELINE: If you are interested in joining our study, please complete the 'Consent Form' included with this invitation pack, and return this to us as soon as possible using the pre-paid envelope enclosed (no stamp required).

When our study team at the University of York receives your 'Consent Form', we will be in touch with you to complete a 'Screening Questionnaire' over the telephone. Your answers to the 'Screening Questionnaire' will determine whether or not you are eligible to take part. If you are eligible, we will then ask you to complete a 'Baseline Questionnaire' whilst you are on the telephone with us. This questionnaire will collect study data about your medical history, your physical, mental, and social wellbeing, and the healthcare services you currently use. Next, we will be in touch with your GP to confirm that there are no health concerns with you joining the study. If there are health concerns, we will send you a letter to let you know that we are unable to enrol you in the study. If there are no health concerns, you will be enrolled in the study, and assigned to one of two groups.]

7. What will I have to do in the study?

For us to be able to measure effects on the quality of life and other aspects of health we need to collect information over time from two types of people: 'Usual Care' participants and 'Yoga' participants. Section 8 below explains these terms.

Half of the people in our study will be 'Usual Care' participants and the other half will be 'Yoga' participants. ***Both types of participants are equally important to us***.

When you join the study, you will have a 50:50 chance of becoming a 'Usual Care' participant or a 'Yoga' participant. In research, the fairest way of doing this is to use a computer programme to randomly choose which type of participant you will be. This decision is not made by our trial team or your GP, and you are not able to choose which type of participant you are.

8. What is the difference between a 'Usual Care' and a 'Yoga' participant?

Usual Care participants: This is usually known as the 'control group'. If you are a 'Usual Care' participant you will continue with any usual care or treatments you may be currently receiving for your health conditions. In other words, it is 'business as usual'- no additional care or treatment will be provided as part of the study. We will follow you over a 12-month period, using a series of questionnaires that we will ask you to complete. At the end of the 12-month study period, half of

the Usual Care participants will be offered a single free session of Gentle Years Yoga. For fairness, the offer (or not) of the free session will also be randomly chosen by a computer.

Yoga participants: This is usually known as the 'intervention group. If you are a 'Yoga' participant, in addition to continuing with your usual care, you will be invited to join a 12-week course of Gentle Years Yoga as follows:

- There will be one 75-minute Gentle Years Yoga class each week for 12 weeks (there may sometimes be a mid-term break in the classes). You will need to be available to attend at least 9 of the 12 classes on offer.
- [INSERT IF FACE-TO-FACE: The classes will be delivered face-to-face in the community. You will therefore need to be able to travel to a yoga class on offer.]
  [INSERT IF ONLINE: The classes will be delivered online via video conferencing. You will therefore need to have the following:
    - Access to a reliable internet connection
    - A suitable electronic device for accessing the online class (e.g., a tablet-size screen or larger; a device with camera, speaker and microphone)
    - Sufficient space at home to perform yoga
    - A sturdy chair for use during the classes]

  [INSERT IF FACE-TO-FACE AND ONLINE BLENDED APPROACH: The classes will be delivered either face-to-face in the community, via online video conferencing, or a mixture of both face-to-face and online classes. This decision will depend on government COVID-19 guidelines and will be confirmed nearer the time of the classes. Because classes may be face-to-face or online, you will therefore need to be able to travel to a yoga class on offer and also have the following:
    - Access to a reliable internet connection
    - A suitable electronic device for accessing the online class (e.g., a tablet-size screen or larger; a device with camera, speaker and microphone)
    - Sufficient space at home to perform yoga
    - A sturdy chair for use during the classes]
- Handouts will be provided to encourage home practice for 15 minutes per day on non-class days.
- Yoga classes will include a maximum of 15 participants, and be delivered by experienced yoga teachers who are qualified in Gentle Years Yoga.
- We will share your contact details and health conditions with your yoga teacher, so that they can contact you to confirm the class details and discuss any questions that you may have about practicing yoga.
- Please note that one of the yoga classes may be observed by a member of our study team for quality assurance purposes.

of this type of yoga are. The information we get from this trial will help us to answer that question.

12. What are the disadvantages of taking part?

All exercise carries a small risk of discomfort or injury, such as temporary muscle soreness or mild muscle strain. For people in our trial receiving the yoga classes, this risk will be minimised by choosing yoga exercises that are appropriate for older adults with long-term health conditions. Additionally, the class will be carefully monitored by an experienced yoga teacher trained specifically to teach Gentle Years Yoga.

13. What will be my GP's involvement?

If you consent to take part in our study, we are required to ask your GP to confirm you are medically fit for the study. If we have difficulties contacting you, we may ask your doctor whether it is appropriate to contact you and for your address, and your GP practice may pass some details to the University of York with your consent. We also have a duty of care to advise your GP of any concerning information relating to your health that comes to light during your participation.

The University of York may need to collect some study-related information about you from your GP practice during the trial, such as updated contact details or health information if you experience any health events as a result of this study.

14. Expenses and payments

Everyone in the study will receive a £5 payment, as cash or a voucher, each time they complete a follow-up questionnaire (at 3, 6, and 12 months). For people who receive the 12-week yoga programme, the classes will be free to attend [INSERT IF FACE-TO-FACE or FACE-TO-FACE AND ONLINE BLENDED APPROACH: but travel expenses will not be reimbursed].

15. Who will know that I am taking part?

The only people who will know you are taking part in the trial are members of the study team, your GP, and the yoga teacher of those who are allocated to the yoga classes. You are free to tell anyone that you are taking part in this study if you wish.

9. Completing follow-up questionnaires for the study

Everyone (i.e. participants in the 'usual care' and 'yoga' groups) will be asked to complete three 'Follow-up Questionnaires'. You will complete these questionnaires at 3, 6, and 12 months after you have joined the study. These questionnaires are very important because they allow us to see if there are any differences between the people who are offered the yoga programme and the people who continued with usual care alone.

The 'Follow-up Questionnaires' will either be posted to you, together with a pre-paid envelope (no stamp required) for returning to us, or we will be in touch with you to complete them over the telephone. On average, each questionnaire takes approximately 30 minutes to complete, and they contain questions about your physical, mental, and social wellbeing. We would also like to know about any healthcare you receive during the study, and will provide a diary for you to record this. If needed, you can ask a friend, relative, or a member of the study team (contact details below) to help you with the questionnaires.

10. Interview sub-study

We would like to interview a few people who agree to take part in the study and a few who decline to take part in the study. These interviews will help us understand people's attitudes towards yoga, their experiences of taking part in our study, or their reasons for not taking part. Interviews will take place as follows:

- For those who take part in the study, we would like to interview you once or twice over the 12 months of the main study.
- For those who decide not to take part in the study but agree to an interview, there will be just one interview.

Interviews will last around 20-90 minutes, take place with a member of our study team either in person, by telephone, or by video conference, and will be recorded with your consent. For more information about the interviews and how to indicate your interest, please [INSERT IF BY POST: see the back of the enclosed Consent Form] [INSERT IF ONLINE: see the electronic consent form].

Please note that interview places are limited; therefore we are unable to interview everyone who is interested. If you have been chosen for an interview, we will send you an information pack within one month of receiving your Consent Form.

11. What are the possible benefits of taking part?

Previous studies have shown that yoga may benefit many different aspects of a person's physical, mental, and social wellbeing. As this is the first detailed investigation of the Gentle Years Yoga programme in older adults with more than one long-term health condition, we currently do not know what the specific effects

16. What happens after the study?

After you have completed the 12-month questionnaire, we will inform you by post when the results are available and where to access them. At this point, you will have the option to contact us if you would like us to provide you with a printed copy. This will consist of a summary of the overall results, but not an individualised report on your performance.

Some of you may be interested in joining a yoga class after the study has finished. To help you with this, when you have completed your 12-week yoga class (for 'Yoga' participants) or 12-month questionnaire (for 'Usual Care' participants) we will provide you with details of Gentle Years Yoga or other suitable yoga classes you could join. As these classes are not part of our study, you would have to organise attending these classes yourself, on a self-pay basis.

The results of this study will be presented to the study funder, and the information will be used to decide whether or not yoga is a suitable treatment for the NHS to provide. The results will also be presented in research reports, scientific conferences and journals. If the funders of this research request that the trial data is made available for other researchers, then we are obliged to do this. All data would be made anonymous so you could not be identified.

17. Who has reviewed the study?

This trial has been reviewed and approved by an independent group of people, the North East - York Research Ethics Committee (Reference Number 19/NE/0072), to make sure the trial respects the safety, rights, wellbeing, and dignity of everyone involved. We have also worked with adults aged over 65 years who have more than one long-term health condition and have experienced the Gentle Years Yoga programme. These people have helped us develop the study documents we send to participants and the processes we use in the trial.

18.What happens to the information you collect from me?

All the information you give us throughout the study will be securely handled and stored in accordance with the Data Protection Act 2018 and General Data Protection Regulation (GDPR) legislation. Your rights to access, change, or move your information are limited, because we need to manage your information in specific ways for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally identifiable information possible. Individuals from the University of York, Northumbria University, and

regulatory organisations (such as our Funder and Sponsor) may request to look at your data records to check the accuracy of our research study.

During the study:

Your contact details will be securely stored at the University of York and only be accessible by authorised members of the study team who need to contact you about the study. Additionally, your GP practice may pass some details to the University of York with your consent.

Your study data (i.e., your consent forms and questionnaires) will be securely stored at the University of York and only be accessible by authorised members of the research team. All paper documents will be placed in a secure storage facility. Data from these questionnaires will be transferred to a computer (electronic data) and stored on password-protected databases. All identifying information (such as your name and address) will be removed from the electronic data and replaced with a unique reference number before it is analysed. All study results, including publications and conference presentations, will be anonymous and no individual will be able to be identified.

Your interview data will be securely stored at Northumbria University, with access restricted to authorised members of the research team. Interview recordings will be electronically stored on a restricted access computer database. Written transcripts from the recordings will have all names and identifying information removed, so that the identity of the participant remains anonymous.

If you are a 'Yoga' participant, your contact details will be securely shared with the yoga teacher from your site, so they can contact you about the classes. The teachers have been contracted to store your details in accordance with data protection legislation. The yoga teacher will send a weekly, anonymised class register, with details of any health events from their classes, to authorised members of the research team at the University of York. This information will allow the study team to record class attendance and safety.

After the study:

All trial data will be archived for a minimum of 10 years after the study has finished. Data access will be restricted to individuals from University of York's Trials Unit, regulatory authorities and the NHS Trust.

For data that had been held at the University of York, all paper documents will be archived there initially, then moved to a University-approved secure off-site storage facility. All electronic data will be securely archived on the university computer network.

For data that had been held at Northumbria University, all interview recordings will be destroyed, and all written transcripts from the interview recordings will be securely archived on the university computer network.

Your information could be used for research in any aspect of health or care and could be combined with information about you from other sources held by

researchers, the NHS or government. Where this information could identify you, the information will be held securely with strict arrangements about who can access the information. The information will only be used for the purpose of health and care research, or to contact you about future opportunities to participate in research. It will not be used to make decisions about future services available to you, such as insurance.

Where there is a risk that you can be identified your data will only be used in research that has been independently reviewed by an ethics committee.

You can find out more about how we use your information at:

- https://www.hra.nhs.uk/information-about-patients/
- https://www.york.ac.uk/healthsciences/research/trials/trials-gdpr/
- https://www.northumbria.ac.uk/about-us/leadership-governance/vice-chancellors-office/legal-services-team/gdpr/

19. What if there is a problem?

If you have any concerns or complaints about any aspect of this study, you should contact the study team (contact details below) who will do their best to answer your questions. If you have any concerns about any part of the study and prefer not to contact a member of the study team, please contact Dr Nick Neave (Faculty Director of Ethics, Northumbria University) on 01912274476 or nick.neave@northumbria.ac.uk

Northumbria University, as Sponsor, has appropriate insurance in place for research activity. In the unlikely event that you suffer any harm as a direct consequence of your participation in this study, individual yoga instructors hold appropriate public liability insurance. In the unlikely event that something does go wrong, there are no special compensation arrangements. If you are harmed and this is due to someone's negligence, then you may have grounds for legal action for compensation, but you may have to pay your legal costs.

20. I have questions or would like more information about the study

We strongly encourage you to contact us if you would like more information about the study, to help you decide whether to take part, or at any point throughout your participation in the study, should you decide to take part. Please see the study team's contact details below. If you would like independent advice about whether or not to take part, or wish to complain formally, you can search for your local Patient Advice and Liaison Service (PALS) at https://www.nhs.uk/service-search/other-services/Patient-advice-and-liaison-services-(PALS)/LocationSearch/363

HOW TO CONTACT US

1. **[INSERT TRIAL COORDINATOR NAME]** (Trial Coordinator)
   Tel: [INSERT TELEPHONE NUMBER]
   Email: [INSERT EMAIL ADDRESS]

2. [**INSERT TRIAL COORDINATOR NAME]** (Trial Coordinator)
   Tel: [INSERT TELEPHONE NUMBER]
   Email: [INSERT EMAIL ADDRESS]
3. [**INSERT TRIAL COORDINATOR NAME]** (Trial Coordinator)
   Tel: [INSERT TELEPHONE NUMBER]
   Email: [INSERT EMAIL ADDRESS]
4. **Dr Garry Tew** (Chief Investigator)
   Email: garry.tew@northumbria.ac.uk

Thank you for reading this information sheet and for considering taking part in this study

This study is funded by the National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme. The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

FUNDED BY NIHR | National Institute for Health Research

Northumbria University NEWCASTLE

UNIVERSITY of York

GP ID ☐☐☐

Participant ID ☐☐☐☐☐

PARTICIPANT CONSENT FORM

The Gentle Years Yoga Trial

If you wish to take part in The Gentle Years Yoga Trial, **please [IF ONLINE: select your GP practice and then] place your initials in each of the boxes below, [IF ONLINE INSERT INSTRUCTIONS FOR FORM SUBMISSION] [IF BY POST: sign and date this form].**

[IF ONLINE insert GP practice dropdown:

Your GP practice: [insert dropdown of names and details of participating GP practices] **]**

*Please **initial** each box*

1. I confirm that I have read and understand the participant information sheet version [2.1 dated [11/12/2020] for the above study and have had the opportunity to ask any questions about the study and any questions have been answered to my satisfaction. Initials

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, and without my medical care or legal rights being affected. Initials

3. I agree to the University of York and Northumbria University holding copies of my consent form, other study related documents and my contact details to allow them to send me questionnaires. Initials

4. I agree to my GP being informed of my participation in the study and being advised of any significant information relating to my health that comes to light during my participation. Initials

5. I understand that relevant sections of my GP medical notes and data collected during the study, may be looked at by individuals from University of York's Trials Unit, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. Initials

6. I understand that the information collected about me will be used to support other research in the future, and may be shared anonymously with other researchers. Initials

7. If I am allocated to the yoga programme, I agree to have my name, phone number and email passed to my assigned yoga teacher who may contact me, and that my yoga teacher will share completed class registers with York Trials Unit. Initials

8. If I am allocated to the yoga programme, I agree to my assigned yoga teacher having details of my medical conditions relevant to my participation in the study, and that my teacher will share details of any adverse health events with York Trials Unit. Initials

9. I am willing to receive telephone calls and voicemail messages to my landline or mobile phone from the study team regarding this study. Initials

10. I am willing to receive emails from the study team regarding this study. Initials

11. **I agree to take part in The Gentle Years Yoga Trial**. Initials

[IF BY POST: PLEASE TURN OVER PAGE]

In addition to the essential statements [IF ONLINE: above] [IF BY POST: over the page], please initial any of the following optional statements you agree with. Your participation in this research study will not be affected if you do not agree with any of these.

Optional areas of participation:

1. I am willing to receive reminder text messages from the study team on my mobile telephone. Initials
2. I am willing to be interviewed by a member of the study team about my attitudes and experiences of this study. Initials

Mandatory section:

To take part in any aspect of the trial it is **essential** that you provide your name, postal address, email address, telephone number, today's date [IF BY POST: and your SIGNATURE] in the boxes below. [IF ONLINE: INSERT RELEVANT INSTRUCTIONS FOR 'SIGNING' THE FORM].

D D / M M / Y Y Y Y

Print title, forename and surname		/		/	2	0			Signature
Title, Forename and Surname [IF BY POST:(please print)]		**Today's Date**							**Signature**

[Original to be kept in Trial Master File; one copy given to participant; and one copy given to the GP to confirm eligibility]

Address [IF BY POST: (PLEASE PRINT):] _____

_____ Postcode: _____

Email Address:

Landline Number:

Northumbria University NEWCASTLE

UNIVERSITY of York

GP ID

Participant ID

Mobile Number:

Please indicate [IF BY POST: by circling] the best time to contact you:
Morning / Lunch / Afternoon / Evening

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The Gentle Years Yoga Trial

Trial Diagram

You are here

[Arrow to be moved down to indicate appropriate study time point at time of sending diagram to participant]

You have received an invitation pack.

If you are interested in taking part, please complete the Electronic Consent Form

If you are not interested in taking part, no further action is required and we will not contact you again.

Research team will contact you to determine if you are eligible to take part, which will involve:

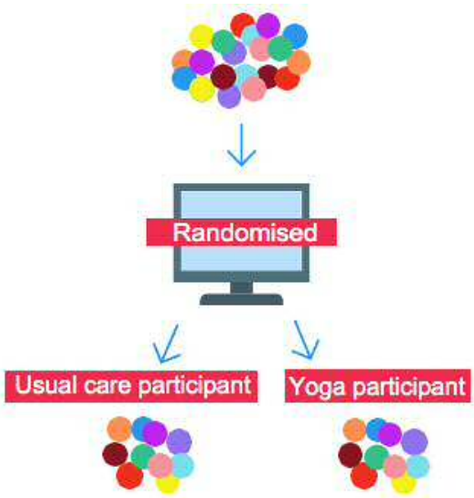
1. Screening Questionnaire
2. Baseline Questionnaire
3. GP Eligibility Check

If you are eligible to take part, you will be enrolled in the study and **randomised** to be a 'Usual Care' or 'Yoga' participant.

If you are not eligible to take part, the team will contact you to let you know. This will be the end of your involvement.

Randomisation is carried out by a computer to allow for a fair comparison to be made between both types of participants. You have a 50:50 chance of being a 'Usual Care' or a 'Yoga' participant.

Usual Care Participant (control group)
Continue with current care and treatments ('Business as usual').



Yoga Participant (intervention group)
Continue with current care and treatments ***plus*** invitation to 12 weekly sessions of Gentle Years Yoga.

Three months after randomisation you will complete the 3 Month Questionnaire

Six months after randomisation you will complete the 6 Month Questionnaire

12 months after randomisation you will complete the 12 Month Questionnaire

End of study
You will be notified when study results become available.

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The Gentle Years Yoga Trial

[INSERT NUMBER] Months Follow-up Questionnaire

(Office use only)

Participant ID Number | | | | | |

Date Sent | | / | | / | |
day / month / year

Completed by researcher ☐

[IF COMPLETING BY TELEPHONE, SKIP THIS SECTION:]Thank you for your continued support in this study.

Your answers to the questions in this questionnaire are very important to the study. Please complete this questionnaire in full and return it, using the pre-paid addressed envelope provided.

If you have need have any queries or need help filling in this form, please contact [INSERT TRIAL COORDINATOR NAME, NUMBER AND EMAIL ADDRESS].

The Gentle Years Yoga Trial
York Trials Unit, ARRC, Lower Ground Floor
Department of Health Sciences
The University of York
York, YO10 5DD

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FUNDED BY NIHR | National Institute for Health Research

[IF COMPLETED BY PHONE, THE RESEARCHER WILL READ THE INSTRUCTIONS TO THE PARTICIPANT:]

[IF COMPLETING BY POST, INSERT: **Please read all the instructions before completing the questionnaire.**]

The information you provide will be treated confidentially. You will not be personally identified in any report or publication resulting from this study.

Please answer ALL the questions. Some of the questions may seem unnecessary or repetitive. However, we would like to reassure you that they are important to the study. Please answer all questions honestly and to the best of your ability.

Please don't deliberate too much. You may feel unsure when answering some of the questions. However, your first instinctive answer is probably the most accurate.

[IF COMPLETING BY POST, INSERT: If you are asked to write in an answer, please print clearly.
Example:

Number of visits	0	8

If you are asked show your response using a tick, please place a tick in the box as clearly as possible.
Example: 

Some questions require you to mark a cross, which enables us to judge the severity of a particular problem.

Do not worry if you make a mistake. Please place a single line through the original entry and write the correct information to the side.

Please use a blue or black pen.]

[DATED BY RESEARCHER IF COMPLETED BY TELEPHONE; ONLY INCLUDE THIS FOR COMPLETION BY POST:
Please enter the date you started this questionnaire (**today's** date)

DD	MM	YYYY

Section 1
The following set of questions is about your general health.
Under each heading, please tick the ONE box that best describes your health TODAY.

1. MOBILITY

I have no problems in walking about ☐
I have slight problems in walking about ☐
I have moderate problems in walking about ☐
I have severe problems in walking about ☐
I am unable to walk about ☐

2. SELF-CARE

I have no problems washing or dressing myself ☐
I have slight problems washing or dressing myself ☐
I have moderate problems washing or dressing myself ☐
I have severe problems washing or dressing myself ☐
I am unable to wash or dress myself ☐

3. USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities)

I have no problems doing my usual activities ☐
I have slight problems doing my usual activities ☐
I have moderate problems doing my usual activities ☐
I have severe problems doing my usual activities ☐
I am unable to do my usual activities ☐

4. PAIN/DISCOMFORT

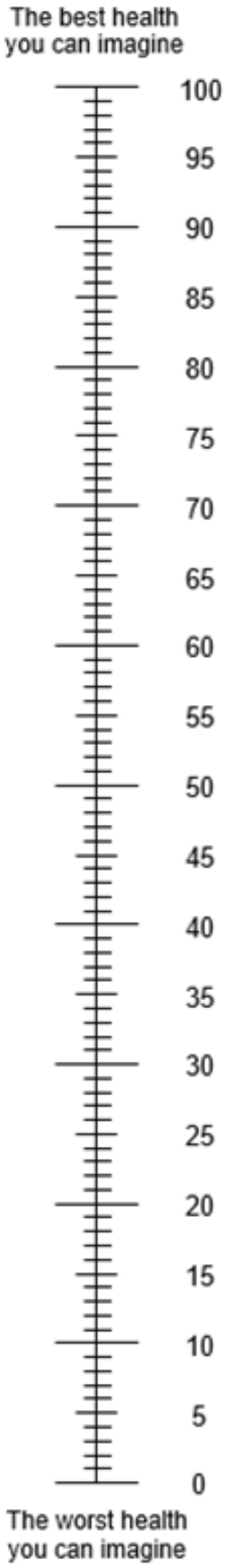
I have no pain or discomfort ☐
I have slight pain or discomfort ☐
I have moderate pain or discomfort ☐
I have severe pain or discomfort ☐
I have extreme pain or discomfort ☐

5. ANXIETY/DEPRESSION

I am not anxious or depressed ☐
I am slightly anxious or depressed ☐
I am moderately anxious or depressed ☐
I am severely anxious or depressed ☐
I am extremely anxious or depressed ☐

- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.
  0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY = ☐



Section 2
Please answer the following sets of questions by placing a tick in the box that best describes your answer.

Over the last 2 weeks, how often have you been bothered by any of the following problems? *(Use ☑ to indicate your answer)*	**Not at all**	**Several days**	**More than half the days**	**Nearly every day**
Little interest or pleasure in doing things	☐ 0	☐ 1	☐ 2	☐ 3
Feeling down, depressed, or hopeless	☐ 0	☐ 1	☐ 2	☐ 3
Trouble falling or staying asleep, or sleeping too much	☐ 0	☐ 1	☐ 2	☐ 3
Feeling tired or having little energy	☐ 0	☐ 1	☐ 2	☐ 3
Poor appetite or overeating	☐ 0	☐ 1	☐ 2	☐ 3
Feeling bad about yourself, or that you are a failure, or have let yourself or your family down	☐ 0	☐ 1	☐ 2	☐ 3
Trouble concentrating on things, such as reading the newspaper or watching television	☐ 0	☐ 1	☐ 2	☐ 3
Moving or speaking so slowly that other people could have noticed. Or the opposite – being so fidgety or restless that you have been moving around a lot more than usual	☐ 0	☐ 1	☐ 2	☐ 3

Over the last 2 weeks, how often have you been bothered by the following problems? *(Use ☑ to indicate your answer)*	**Not at all**	**Several days**	**More than half the days**	**Nearly every day**
Feeling nervous, anxious or on edge	☐ 0	☐ 1	☐ 2	☐ 3
Not being able to stop or control worrying	☐ 0	☐ 1	☐ 2	☐ 3
Worrying too much about different things	☐ 0	☐ 1	☐ 2	☐ 3
Trouble relaxing	☐ 0	☐ 1	☐ 2	☐ 3
Being so restless that it is hard to sit still	☐ 0	☐ 1	☐ 2	☐ 3
Becoming easily annoyed or irritable	☐ 0	☐ 1	☐ 2	☐ 3
Feeling afraid as if something awful might happen	☐ 0	☐ 1	☐ 2	☐ 3

Please respond to each question or statement by ticking one box per row.

Physical Function	Without any difficulty	With a little difficulty	With some difficulty	With much difficulty	Unable to do
Are you able to do chores such as vacuuming or yard work?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Are you able to go up and down stairs at a normal pace?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Are you able to go for a walk of at least 15 minutes?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Are you able to run errands and shop?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Anxiety **In the past 7 days…**	Never	Rarely	Sometimes	Often	Always
I felt fearful	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
I found it hard to focus on anything other than my anxiety	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
My worries overwhelmed me	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
I felt uneasy	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Depression **In the past 7 days…**	Never	Rarely	Sometimes	Often	Always
I felt worthless	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
I felt helpless	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
I felt depressed	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
I felt hopeless	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Fatigue **During the past 7 days…**	Not at all	A little bit	Somewhat	Quite a bit	Very much
I feel fatigued	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
I have trouble starting things because I am tired	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
How run-down did you feel on average?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
How fatigued were you on average?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Sleep Disturbance **In the past 7 days…**	Very poor	Poor	Fair	Good	Very good
My sleep quality was	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
In the past 7 days…	Not at all	A little bit	Somewhat	Quite a bit	Very much
My sleep was refreshing	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
I had a problem with my sleep	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
I had difficulty falling asleep	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Ability to Participate in Social Roles and Activities	Never	Rarely	Sometimes	Usually	Always
I have trouble doing all of my regular leisure activities with others	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
I have trouble doing all of the family activities that I want to do	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
I have trouble doing all of my usual work (include work at home)	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
I have trouble doing all of the activities with friends that I want to do	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

Pain Interference **In the past 7 days…**	Not at all	A little bit	Somewhat	Quite a bit	Very much
How much did pain interfere with your day to day activities?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
How much did pain interfere with work around the home?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
How much did pain interfere with your ability to participate in social activities?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
How much did pain interfere with your household chores?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Pain Intensity **In the past 7 days…**					
How would you rate your pain on average?	☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ 0 1 2 3 4 5 6 7 8 9 10 No pain				Worst pain imaginable

The next questions are about how you feel about different aspects of your life. For each one, tell me how often you feel that way.
(Tick one box for each question).

	Hardly ever or never	**Some of the time**	**Often**
How often do you feel that you lack companionship?	☐	☐	☐
How often do you feel left out?	☐	☐	☐
How often do you feel isolated from others?	☐	☐	☐

How often do you feel lonely?
(Please tick one box only)

☐	☐	☐	☐	☐
Often or Always	Some of the time	Occasionally	Hardly ever	Never

Falls Incidence
This section asks about any falls you have had.
For the sake of this study we define a fall as “an unexpected event in which you come to rest on the ground, floor or lower level".

1. Have you fallen in the past **[INSERT NUMBER] months**?
   (Please tick one box only)

YES	NO
☐	☐

1a. If yes, how many falls did you have in the past **[INSERT NUMBER] months**?

☐☐ Falls

1b. If yes, were you required to stay in hospital overnight as a result of a fall?

YES	NO
☐	☐

Section 3
This section is about the health care you have received in the last [INSERT NUMBER] months

Care from the NHS NOT in the hospital

In the past **[INSERT NUMBER] months**, have you had any contact with the following health professionals in the community? Please tick yes OR no for each service. If "**Yes**", please indicate how often you had contact with them.

Health Professional	Definition	Contact with them?	Number of Visits (If none enter "00")
GP visit at practice	You saw a GP at the practice	☐ Yes ☐ No	☐☐
GP visit at home	A GP visited you in your home	☐ Yes ☐ No	☐☐
GP consultation on the phone	A GP spoke to you over the phone	☐ Yes ☐ No	☐☐
Nurse visit at practice	A nurse who works at GP practice who saw you in the GP practice	☐ Yes ☐ No	☐☐
Nurse visit at home	A nurse who works at GP practice who visited you at home	☐ Yes ☐ No	☐☐
Nurse consultation over the phone	A nurse who works at GP practice who spoke to you over the phone	☐ Yes ☐ No	☐☐
District nurse visit at practice	A nurse who works in the community who saw you at GP practice	☐ Yes ☐ No	☐☐
District nurse visit at home	A nurse who works in the community who visited you at home	☐ Yes ☐ No	☐☐
District nurse consultation over phone	A nurse who works in the community who spoke to you over the phone	☐ Yes ☐ No	☐☐
Physiotherapist	A physiotherapist who works in the community who you saw at their	☐ Yes ☐ No	☐☐

	practice, your home, or spoke to over the phone		
Mental health services (e.g. counselling)	A mental health service professional who works in the community who you saw at their practice, your home, or spoke to over the phone	☐ Yes ☐ No	☐☐

Care from the NHS IN the hospital

In the past **[INSERT NUMBER] months**, have you visited a NHS hospital (not private hospital) for any of the reasons below? Please tick yes OR no for each service. If "**YES**", please indicate how often for each type of visit. If you have stayed overnight, please state the total number of nights in the final column.

Hospital Visits	Definition	Had a visit?	Number of visits (If none enter "00")	Total number of nights stayed over
Physiotherapist	Appointment with a physiotherapist at the hospital	☐ Yes ☐ No	☐☐	
Mental health service	Appointment with mental health services at the hospital	☐ Yes ☐ No	☐☐	
Other out-patient appointments	Any other specialist or service in a hospital that did not require you to stay overnight (e.g., blood tests, x-rays, scans, having plaster casts fitted, occupational therapy, and podiatry)	☐ Yes ☐ No	☐☐	
Day case appointment	A planned admission to hospital, where you were given a bed but you were not required to stay overnight (e.g., some cancer treatments/chemotherapy, endoscopy, colonoscopy,	☐ Yes ☐ No	☐☐	

	invasive x-rays/scan procedures)			
Accident & Emergency visit that did not require a stay in hospital	Attended A&E, but you were not required to stay overnight	☐ Yes ☐ No	☐☐	
Planned In-patient stay in NHS hospital (not via A&E)	A stay in hospital overnight that was scheduled in advance, because it did not require a medical emergency. **In case of multiple stays** (e.g. you had a first in-patient stay of 2 nights, and a second in-patient stay of 1 night) **please report as follows:** *Number of visits: 2* *Total number of nights: 3*	☐ Yes ☐ No	☐☐	☐☐
Accident & Emergency visit that required a stay in hospital	Attended A&E, and you were required to stay in hospital overnight. **In case of multiple A&E visits** (e.g. first A&E visit requiring 1 night, and a second A&E visit requiring 1 night) **please report as follows**: *Number of visits: 2* *Total number of nights: 2*	☐ Yes ☐ No	☐☐	☐☐

Private Treatments

We would like you tell us about any additional medical treatment you have received, which you paid for (e.g. personal cost or private insurance health care).

In the past **[INSERT NUMBER] months**, have you had any contact with the following health professionals? Please tick yes OR no for each service. If "**Yes**", please indicate how often you had contact with them.

Health Professional	Contact with them?		Number of Visits
Seen Private GP	☐ Yes	☐ No	☐☐
Seen a Private physiotherapist	☐ Yes	☐ No	☐☐

Seen a Private specialist for a mental health service	☐ Yes ☐ No	☐☐

Section 4
This section is about your participation in yoga

1a. Have you participated in any face-to-face or online yoga classes in the past [INSERT NUMBER] months?
(Please place a tick in all boxes that apply)

☐ NO
☐ YES – Gentle Years Yoga classes
☐ YES – other group-based yoga classes
☐ YES – one-to-one yoga sessions

1b. If you answered 'YES' to the above question please indicate the number of classes/sessions you have attended in the past [INSERT NUMBER] months.

☐☐

2a. Have you been doing self-managed yoga practice at home in the past [INSERT NUMBER] months (including as part of the Gentle Years Yoga programme)?
(Please place a tick in one box only)

YES ☐ NO ☐

2b. If you answered 'YES' to the above question, please indicate the number of self-managed home-based yoga sessions you completed in a typical week (7 days) and the usual duration (length) of each of these sessions.

Number of home yoga sessions done in a typical week: ☐☐

Usual duration of each home yoga session (in minutes): ☐☐☐

[INSERT SECTIONS 5 AND 6 JUST FOR THE 12 MONTH FOLLOW-UP QUESTIONNAIRE]

Section 5
In this section we would like to know about your preferences for the treatments that were on offer in this study.

1. Based upon your experiences in the trial, which treatment would you now prefer? (please tick one box only)

Yoga + Usual Care	Usual Care	No Preference
☐	☐	☐

Section 6
As this is the final follow-up and your involvement in the study is drawing to an end, we would like to know if you would be interested in us getting in touch to let you know about the results of the study when they become available. Please indicate your preferences by putting a tick in the appropriate box below.

1. Are you interested in knowing about the results of the study?

YES	NO
☐	☐

[INSERT THE FOLLOWING AT THE END OF ALL THE QUESTIONNAIRES]:

Can you please indicate below what level of support you had completing this questionnaire by putting a tick in the box next to the most appropriate statement.

I had help completing this questionnaire ☐

I completed this questionnaire on my own ☐

Thank you for completing this questionnaire.
Please return this questionnaire in the pre-paid envelope provided.

The Gentle Years Yoga Trial - Health Care Diary

Health Care Received - Please record your healthcare visits in this diary to help you complete the next questionnaire. Thank you.

Health Care Service	Definition	Date of Visit (dd/mm/yy)	Date of Visit (dd/mm/yy)	Date of Visit (dd/mm/yy)	Date of Visit (dd/mm/yy)	Date of Visit (dd/mm/yy)
Care from the NHS NOT in the hospital						
GP visit at practice	You saw a GP at the practice					
GP visit at home	A GP visited you in your home					
GP consultation on the phone	A GP spoke to you over the phone					
Nurse visit at practice	A nurse who works at GP practice who saw you in the GP practice					
Nurse visit at home	A nurse who works at GP practice who visited you at home					
Nurse consultation over the phone	A nurse who works at GP practice who spoke to you over the phone					
District nurse visit at practice	A nurse who works in the community who saw you at GP practice					
District nurse visit at home	A nurse who works in the community who spoke to you over the phone					
District nurse consultation over the phone	A nurse who works in the community who spoke to you over the phone					

Physiotherapist in the community	A physiotherapist who works in the community who you saw at their practice, your home, or spoke with over the phone					
Mental health services (e.g. counselling) in the community	A mental health service professional who works in the community who you saw at their practice, your home, or spoke with over the phone					
Care from the NHS IN the hospital						
Mental health services	Appointment with mental health services at the hospital					
Physiotherapist	Appointment with physiotherapist at the hospital					
Other out-patient appointments	Any other specialist or service in a hospital that did not require you to stay overnight (e.g., blood tests, x-rays, scans, having plaster casts fitted, occupational therapy, and podiatry					
Day case appointment	A planned admission to hospital, where you were given a bed but you were not required to stay overnight (e.g., some cancer treatments/chemotherapy, endoscopy, colonoscopy, invasive x-rays/scan procedures					

Planned in-patient stay in NHS hospital (not via A&E)	A stay in hospital overnight that was scheduled in advance, because it did not require a medical emergency *For each, please indicate how many nights you stayed in hospital*					
Accident & Emergency visit that required a stay in hospital	Attended A&E and you were required to stay in hospital *For each, please indicate how many nights you stayed in hospital*					
Accident & Emergency visit that did not require a stay in hospital	Attended A&E, but you were not required to stay overnight					
Private Treatments						
Private GP appointment						
Private physiotherapist appointment						
Appointment with a private specialist for a mental health service						