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THE BRITISH WHEEL OF
YOGA®

The Gentle Years Yoga Trial



Yoga Teacher Research Delivery Manual

V4.0

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for Health Research

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PLEASE NOTE: Due to the COVID-19 pandemic, the research team is primarily working from home and relying on remote access systems, with limited office access. Our response times may be slightly longer than usual, but we will get back to you as soon as we can.

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Abbreviations

BWY	British Wheel of Yoga
GP	General practitioner
GYG	Gentle Years Yoga
HRQoL	Health-Related Quality of Life
ICO	Information Commissioner's Office
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health Research
PE	Process Evaluation
RCT	Randomised controlled trial
YTU	York Trials Unit

Preface

Welcome to the **Gentle Years Yoga (GY)** trial.

This trial is funded by a National Institute for Health Research (NIHR) Health Technology Assessment Grant (17/94/36), to investigate the effectiveness of a 12-week yoga programme for older adults with multiple health conditions.

To ensure the trial is delivered consistently across all trial sites and meets national and international recommendations for intervention justification and description (Hoffmann, Glasziou et al. 2014, National Institute for Health and Care Excellence 2016), we have developed a training manual for yoga teachers, outlining intervention delivery and research trial procedures.

The aims of this manual are to:

- Supplement the yoga training materials provided by the GY yoga supervisors
- Provide an overview of the GY trial and your role in delivering the trial intervention
- Provide a reference for trial-specific processes and procedures
- Enable you to be sufficiently informed about the GY trial to answer simple questions from participants, and to know who to refer participants to for further information or advice.

Chapter 1. The role of yoga in older adults with multimorbidity

1.1 Multimorbidity

1.1.1 Multimorbidity in older adults

Multimorbidity is defined as having two or more long-term (chronic) physical and/or mental health conditions (National Institute for Health and Care Excellence, 2016). This health presentation constitutes one of the biggest challenges facing health systems internationally, as multiple disease care becomes the norm in an expanding ageing society (Mangin et al., 2012; Goodwin et al., 2014).

The prevalence of multimorbidity is high in older adults (adults over 65 years of age), particularly those from socioeconomically deprived areas. A large study of the Scottish population indicated up to 65% of adults aged 65-84 years to be multimorbid (Barnett et al., 2012). Additionally, the likelihood of having a mental health condition, such as depression, increases in line with the number of physical disorders a person has (Barnett et al., 2012).

Multimorbidity leads to poorer health outcomes. Having multiple chronic health conditions is associated with reductions in life expectancy, quality of life, and physical and mental wellbeing (Wolff et al., 2002; Salisbury et al., 2011). Multimorbid individuals also consume a disproportionately large share of healthcare resources (McPhail, 2016; Eckardt et al., 2017).

1.1.2 Clinical guidelines for management of multimorbidity

In the UK, the National Institute for Health and Care Excellence (NICE) guidelines target improving the quality of life of individuals with multimorbidity, by reducing treatment burden, adverse events, and unplanned or uncoordinated care (National Institute for Health and Care Excellence, 2016). They advise individualised management, addressing the impact of multimorbidity on a patient's mental health, well-being, and quality of life. However, no specific management strategies or interventions are promoted in these guidelines.

1.1.3 Research evidence for management of multimorbidity

The evidence base for best management of multimorbidity in older adults is weak. A recent review found only 18 randomised controlled trials (RCTs) worldwide evaluating interventions for improving multimorbidity outcomes in primary care and community settings (Smith et al., 2016). Interventions were primarily organisational, based around care delivery; with only six studies targeting patient self-management strategies, such as support groups. Across all 18 studies there was little or no difference in clinical outcomes (moderate certainty evidence); however, improvements were noted for mental health outcomes (high certainty), patient-reported outcomes (moderate certainty), and functional outcomes (Gitlin et al., 2006; Garvey et al., 2015).

This current evidence base highlights the need for further research to determine the clinical and cost effectiveness of interventions that are ideally simple, generalisable, and able to address multiple health conditions simultaneously. NICE recommendations for future research include the need for large, well-designed trials of holistic interventions, targeting relevant patient-reported outcomes such as quality of life (National Institute for Health and Care Excellence, 2016).

1.2 Yoga as a therapeutic practice

Yoga presents as a candidate intervention to address current gaps in the evidence base for older adults with multimorbidity, while meeting NICE recommendations for management of multimorbidity.

Yoga originated thousands of years ago in India, as an integrated physical, mental, and spiritual practice based on ancient Vedic philosophy. During the 20th century, yoga became increasingly recognised outside India, and over the past decades has gained popularity as a system for promoting health and wellbeing.

There are many different styles or schools of yoga, each with a different emphasis on, and approach to, practice. Typically, yoga practice incorporates physical postures (asana) with mental or spiritual elements such as breathing (pranayama), relaxation, concentration (dharana) and meditation (dhyana). For this reason, yoga is considered a mind-body practice.

1.2.1 Yoga for the management of chronic health

Evidence suggests that yoga practice may have therapeutic health benefits. In 2017, the Cochrane Library published a special collection of systematic reviews of yoga for chronic health conditions. Yoga was found effective for improving a range of health outcomes, including, but not limited to, non-specific low back-related pain and function (Wieland et al., 2017); asthma-related symptoms and quality of life (Yang et al., 2016); and breast cancer-related fatigue and sleep disturbance (Cramer et al., 2017). Importantly, a comprehensive review of clinical trials found yoga was not associated with any serious adverse events and may be considered a safe form of exercise across a range of physical and mental health conditions (Cramer et al., 2015).

1.2.2 Yoga for older adults

There are limited studies investigating the health benefits and safety of yoga specifically in older populations. However, research findings to date are encouraging. For example, a 2012 systematic review of 16 studies (n = 649) (Patel et al., 2012), and a more recent trial of 118 participants (Gothe and McAuley, 2015) suggest that yoga may provide greater improvements in physical functioning and self-reported health status than conventional physical activity interventions in older adults. More recently, a systematic review of six trials (n=307) of relatively high methodological quality reported that yoga interventions had small but beneficial effects on balance, and medium effects on physical mobility in people aged 60 and over (Youkhana et al., 2015).

In summary, the data presented above offer support for the beneficial effects of yoga in both older adults and for several age-related health conditions. However, many of the previous studies had limitations, including small sample sizes, a single yoga teacher delivering the programme, and short-term follow-up. Robust economic evaluations of yoga are also limited, although a recent systematic review concluded that “medical” yoga is likely to be a cost-effective option for low back pain (Andronis et al., 2017). To address these gaps in evidence and methodology, we have developed the Gentle Years Yoga Trial.

Chapter 2. The Gentle Years Yoga Programme

2.1 History of the Gentle Years Yoga Programme

In 2009 the British Wheel of Yoga (BWY) Gentle Years Yoga® (GY) programme was developed by the Yorkshire Yoga & Therapy Centre, to cater specifically for the needs of people with age-related health conditions such as osteoarthritis, hypertension, and cognitive impairment. In response to an initiative from the BWY's Focus Group on Older People, the programme was further refined in 2015 with the development of a GY teacher training course. This course studies the physiology of older adults and age-related conditions, and incorporates activities explicitly designed to strengthen the core and lower limbs, develop balance skills/proprioception/hand-eye coordination, and improve working memory.

GY is based on Hatha Yoga, incorporating traditional physical poses with breathing exercises, meditation, and relaxation. Adaptations to challenging Hatha Yoga poses have been made, to enable inactive, multimorbid older adults to safely participate whilst still reaping the fitness, health, and wellbeing benefits of yoga. The GY programme involves once-weekly, 75-minute, group-based yoga sessions led by a trained GY teacher. Additionally, daily self-managed home practice is encouraged and supported through provision of supplementary handouts.

In 2017, the standardised, quality assured GY teacher training course was launched nationally through the BWY, a National Governing Body with a nationwide network of over 5,000 qualified yoga teachers.

2.2 Research evidence for the GY programme

In 2016, a 10-week pilot trial of the GY programme funded by the BWY and Awards for All was conducted in Harrogate, involving 52 community-dwelling, multi-morbid, inactive older adults (mean age 75 years) (Tew et al. 2017). Participants presented with up to six chronic health conditions, most commonly osteoarthritis, hypertension, and depression. The programme was delivered across four community venues, by yoga teachers specifically recruited and trained for the study.

Study results indicated feasible levels of attendance (67% of participants attending ≥8 of 10 sessions), and the potential for clinically important improvement in health-related quality of life at 3 months post-randomisation. A grant application submitted to the NIHR was successful, funding the current large-scale, fully powered trial.

2.3 Future implementation of the GY programme

If the current trial demonstrates the GY programme to be clinically and cost effective, there is potential for implementation in the NHS. The focus of our study is consistent with the NIHR themed call on complex health and care needs in older people; specifically, regarding testing interventions focussed on promoting healthy ageing and preventing ill health.

Additionally, yoga presents as a suitable option for the increasing national focus on social prescribing by general practitioners; and is positively promoted as an exercise option by the NHS (NHS, 2019).

Chapter 3. The Gentle Years Yoga Trial

3.1 Study overview

The Gentle Years Yoga (GY) Trial is a UK-based research study that aims to determine the clinical and cost effectiveness of the BWY Gentle Years Yoga© programme plus usual care compared with usual care alone in adults aged 65 years or older with two or more long-term medical conditions. The trial comprises a multi-centre, two-arm, randomised controlled trial (RCT), with an embedded process evaluation study (**Figure 1**). Our recruitment target is 586 participants.

The GY Trial is being delivered in two phases: an internal pilot phase, and a main trial phase. The internal pilot evaluated the delivery and acceptability of the 12-week GY intervention, via staff and participant interviews, and monitoring of recruitment and retention rates. Following favourable outcomes in the pilot phase, the main phase of the trial is now being undertaken.

3.1.1. Process evaluation

Concurrent to the internal pilot and main trial phases, a process evaluation will be conducted with participants, staff, and yoga teachers, to investigate the determinants of implementation, intervention experiences, and optimal strategies for embedding and normalising the yoga intervention for wider roll-out (**Figure 1**). This evaluation will involve interviews with a selection of trial participants, teachers, and staff; and the observation of a selection of yoga classes across the trial sites. Further information is provided in Chapter 4, Section 4.7.

3.2 Objectives and outcome measures

The primary objective of the GY trial is to evaluate the clinical effectiveness of the 12-week GY programme plus usual care in older adults with multimorbidity compared to usual care alone. The primary outcome to evaluate effectiveness is health-related quality of life (HRQoL), measured using the EQ-5D-5L utility index score. HRQoL will be assessed at baseline and 3, 6, and 12 months after randomisation, and the primary endpoint will be the overall difference in score over the 12 months.

A range of secondary objectives will also be explored, and measured at 3, 6, and 12 months. These include intervention effects on outcomes of depression, anxiety, loneliness, and falls incidence; intervention safety; and intervention cost-effectiveness.

3.3 Recruitment and randomisation

Participants will be recruited solely from primary care sites. To reduce travel burden for participants attending courses in person, we will target GP practices that are within a reasonable distance of intended class venues and serviced by good public transport routes. For courses delivered on-line via Zoom, we may be targeting GP practices from across the UK, so participants could join from a variety of locations.

The GP practices will identify potentially eligible patients from their database and mail out study invitation packs.

Following receipt of informed consent, screening and baseline data collection and GP confirmation of eligibility, participants will be randomised on a 1:1 basis to one of the two trial arms: the GY programme and usual care (n=293) or usual care alone (n=293). Participants allocated to the usual

care control group will be further randomised on a 1:1 basis to receive a single free session of GYY after completion of their 12-month follow-up questionnaire (**Figure 1**).

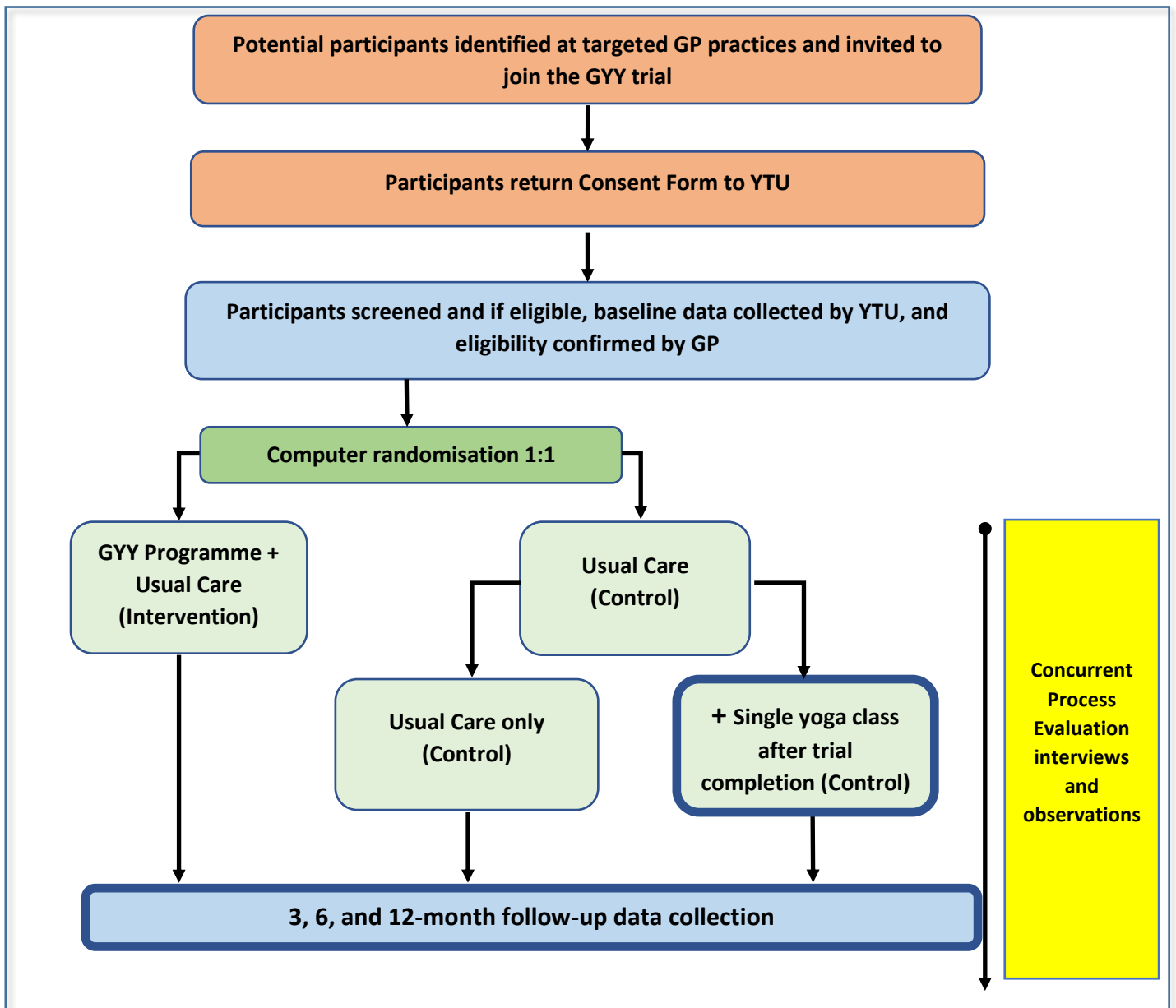


Figure 1. Study overview

3.4 Eligibility criteria

Participant eligibility criteria are detailed in **Table 1**. The target population is older adults with multimorbidity, defined as having two or more chronic health conditions. We will include people aged 65 years and over, who are community-dwelling, and who have two or more chronic conditions from a pre-specified list.

In order to maximise generalisability of the study findings and avoid unfair exclusion based on health and age demographics, the exclusion criteria have been kept to a minimum. Therefore, there is no upper limit on a participant’s age or number of concurrent chronic health conditions.

Table 1. Eligibility Criteria

Inclusion criteria	Exclusion criteria
<ul style="list-style-type: none"> • Aged 65 years or older • Community dwelling (including sheltered housing living with support) • Two or more medical conditions from the following list: ▶ Anxiety ▶ Arthritis ▶ Asthma or Chronic obstructive pulmonary disease ▶ Atrial fibrillation ▶ Bowel problems ▶ Cancer ▶ Cardiovascular disease ▶ Chronic kidney disease ▶ Dementia ▶ Depression ▶ Diabetes ▶ Epilepsy ▶ Fibromyalgia ▶ Multiple sclerosis ▶ Osteoporosis or osteopenia ▶ Parkinson’s disease ▶ Stroke ▶ Sensory conditions 	<ul style="list-style-type: none"> • Unable to attend one of the yoga courses (≤ 8 classes; lack of IT access) • Attended yoga classes twice a month or more in the previous 6 months • Contraindications to yoga participation • Severe mental health problem • Learning disability • Unable to read or speak English • Unable to provide consent • Unable to complete and return valid baseline questionnaire • No more than one patient per household • Currently enrolled in another study for which concurrent participation is deemed inappropriate

3.5 Trial arms

Participants taking part in the GYY Trial will be randomised to one of two trial arms: usual care (Control) or GYY programme plus usual care (Intervention).

3.5.1 Usual Care (Control)

Participants randomly allocated to the Control group will continue with their usual care for the duration of the study.

Usual care is defined as “*The wide range of care that is provided in a community whether it is adequate or not, without a normative judgment*” (Smelt et al. 2010). Pragmatically, this means that participants will not be provided with extra treatments or activities specifically in the context of the GYY Trial. However, they are entitled to continue with, or begin, treatments or activities provided by primary care, secondary care, community, and social services.

A subset of usual care participants will additionally be randomised to receive a single yoga class after they have completed the trial (**Figure 1**). These participants will be contacted about attending this class after they have returned the 12-month questionnaire.

3.5.2 GYY Programme (Intervention)

Participants randomly allocated to the Intervention group will be invited to attend a 12-week course of teacher-led, group-based GYY classes. The class is mainly chair-based; either seated or using the chair for support. All practices are adaptable to address the specific health needs of each participant. Additionally, participants will be encouraged to engage in regular, self-directed home practice.

Details of the GYY Programme, together with supplementary resources (e.g. handout on the Digestive system), have been supplied to you by the GYY yoga supervisors (Jenny Howsam and Laura Bissell).

The 12-week courses will be delivered either face-to-face in a community-based venue (e.g. yoga centre, community hall, leisure centre), or via the on-line platform Zoom. Mode of delivery will be dictated by COVID-19 recommendations and GP capacity to identify participants at the time of recruitment. Regardless of the setting, all classes will be delivered by a trained GYY yoga teacher, with a maximum of 15 participants in face-to-face classes and 12 participants in on-line classes.

Chapter 4. GYY teacher responsibilities

Your role in the GYY programme is the delivery of the 12-week GYY yoga programme to participants in the intervention arm of the study.

The planning, content, and delivery of the GYY classes will be familiar to you, as qualified GYY yoga teachers. However, the delivery of GYY classes within the context of a randomised controlled trial involves additional processes and documentation beyond the scope of your normal community classes.

This chapter outlines these trial-specific elements, **designed to ensure consistent delivery and reporting of the GYY trial across all study sites**. If you have any queries regarding these, please don't hesitate to contact us, using the details given on Page 3.

4.1 Minimising bias

Bias occurs in randomised controlled trials when control participants are exposed to, or gain access to, the treatment being delivered to the intervention participants. In relation to our study, this would occur if any of our control group participants attended the GYY classes.

The introduction of bias would have negative repercussions for our trial. Firstly, it would reduce the validity, or robustness of our trial design. Secondly, it could minimise any differences in outcomes between the two participant groups, making it difficult for us to determine if the GYY classes are effective compared to usual care.

To reduce the likelihood of bias, we request that you adhere to the following procedures:

- GYY teachers must remain independent of recruitment, randomisation, and data collection procedures
- If anyone expresses an interest in participating in the trial, please direct them to their GP or the GYY trial management team at YTU for further information
- If any participants ask you for help with completing the study questionnaires please direct them to the GYY trial management team at YTU, who will be able to assist them
- Ensure your GYY trial classes are only delivered to the GYY participants who have been randomly assigned to receive the yoga classes, as per the details supplied to you by YTU
- Trial participants randomised to the usual care control group **must not** attend the GYY Trial classes. While some participants may be upset they were not allocated to receive yoga, it is important to remember that all participants volunteered and provided informed consent to participate in the trial with the knowledge they may not receive the yoga intervention
- If anyone approaches you expressing concerns or frustration about not being offered the GYY programme as part of the trial, please direct them to the GYY Trial management team at YTU, who will be able to answer their questions

4.2 Organising the yoga classes

4.2.1 Face-to-face delivery of group-based yoga classes

It is your responsibility to arrange a venue suitable for an older adult, multi-morbid population.

Considerations for the venue include:

- Non-step access
- Good lighting
- Adequate heating
- Suitable floor coverings
- Access to public transport
- Chairs suitable for the yoga practices
- Venue has adequate public liability insurance

Following the removal of most COVID-19 restrictions in July 2021, permission to resume face to face delivery of GYY yoga classes was obtained; on condition that the yoga teachers complete a BWY venue risk assessment form. **Please complete the BWY risk assessment form (Appendix 1) for your venue as soon as possible and return to Jenny Howsam.** Sponsor approval will then be sought by the GYY study team at YTU and confirmation sent to you once a reply has been received.

If there are any issues with venue availability or safety, please liaise with Jenny Howsam to arrange a suitable and timely replacement. Likewise, any issues with completion of the risk assessment form please contact Jenny.

4.2.2 On-line delivery of yoga classes

All on-line trial classes will be delivered via Zoom. If needed, you will be provided with a large screen monitor to ensure you are able to see all participants clearly, to ensure they are practicing safely within the limitations of their health conditions. Please refer to your BWY guidelines for delivering on-line classes.

4.3 Covering absences

You are contracted to provide delivery of the 12-week yoga programme at your specific site. However, we understand there may be instances where you are unable to provide a class, for example due to illness.

To avoid disruption to participants, and to adhere to our 12-week schedule, it is preferable to arrange a substitute teacher rather than cancel a class.

As we have a limited number of GYY teachers who have been trained to deliver this trial intervention, it is essential to provide us with as much notice as possible of your absence, to enable time for us to find a replacement teacher. **Please contact Jenny Howsam** as soon as possible, to discuss options.

4.4 Dealing with non-attendance

All our trial participants are important to us and good communication is essential to ensure they remain engaged in the GYY Trial over the 12-month period from their randomisation to their final follow-up questionnaire. In relation to your role in the GYY trial, it is important to support participants to attend as many of the 12 yoga classes as possible.

There are many reasons why a participant may stop attending your yoga classes, which may or may not be related to the GYY trial. To optimise and encourage attendance, we request you follow standard procedures for dealing with non-attendance, as outlined below and in **Figure 2**:

- i. If a participant does not attend a GYY session, record this in the Class **Attendance Register** and return to the York Trials Team (**Appendix 2**). In addition, record weekly attendance in the **Class Participant Details and Reference Class List (Appendix 3)** which you are to keep for your personal record of participant attendance.
- ii. If a participant does not attend **two** consecutive GYY sessions **and** has not notified you previously or within 24 hours after the class, contact them within the week following the second missed class. If applicable, leave a voicemail message asking them to contact you.
- iii. If you are **not able** to contact the participant **and** they do not attend the following week's class (missing three consecutive sessions), then telephone again, leaving a message if applicable. If again you are not able to contact the participant **and** they do not attend the following week's class (missing four consecutive sessions) please inform the GYY trial management team at YTU via telephone or email **within one working day**. For data protection reasons, please do not leave the participant's name in any emails or voice mail messages.
- iv. If you **are** able to contact the participant, take the following actions as applicable:
 - If the participant is concerned about their ability to take part in the GYY classes, reassure them of the safety and appropriateness of the yoga practices for people of their age group and associated health conditions.
 - If the participant indicates pragmatic difficulties in attending classes, for example transport (face-to-face classes) or IT issues (on-line classes), discuss possible options for overcoming these.
 - If the participant has questions or concerns regarding the conduct of the classes or trial, ask if they would like to discuss these with a member of the GYY research team.
 - If the participant wishes to withdraw from the trial, follow the appropriate reporting procedure as detailed in Chapter 8.
 - If the participant reports experiencing an event meeting the definition of an Adverse Event or Serious Adverse Event, follow the appropriate reporting procedure as detailed in Chapter 7.

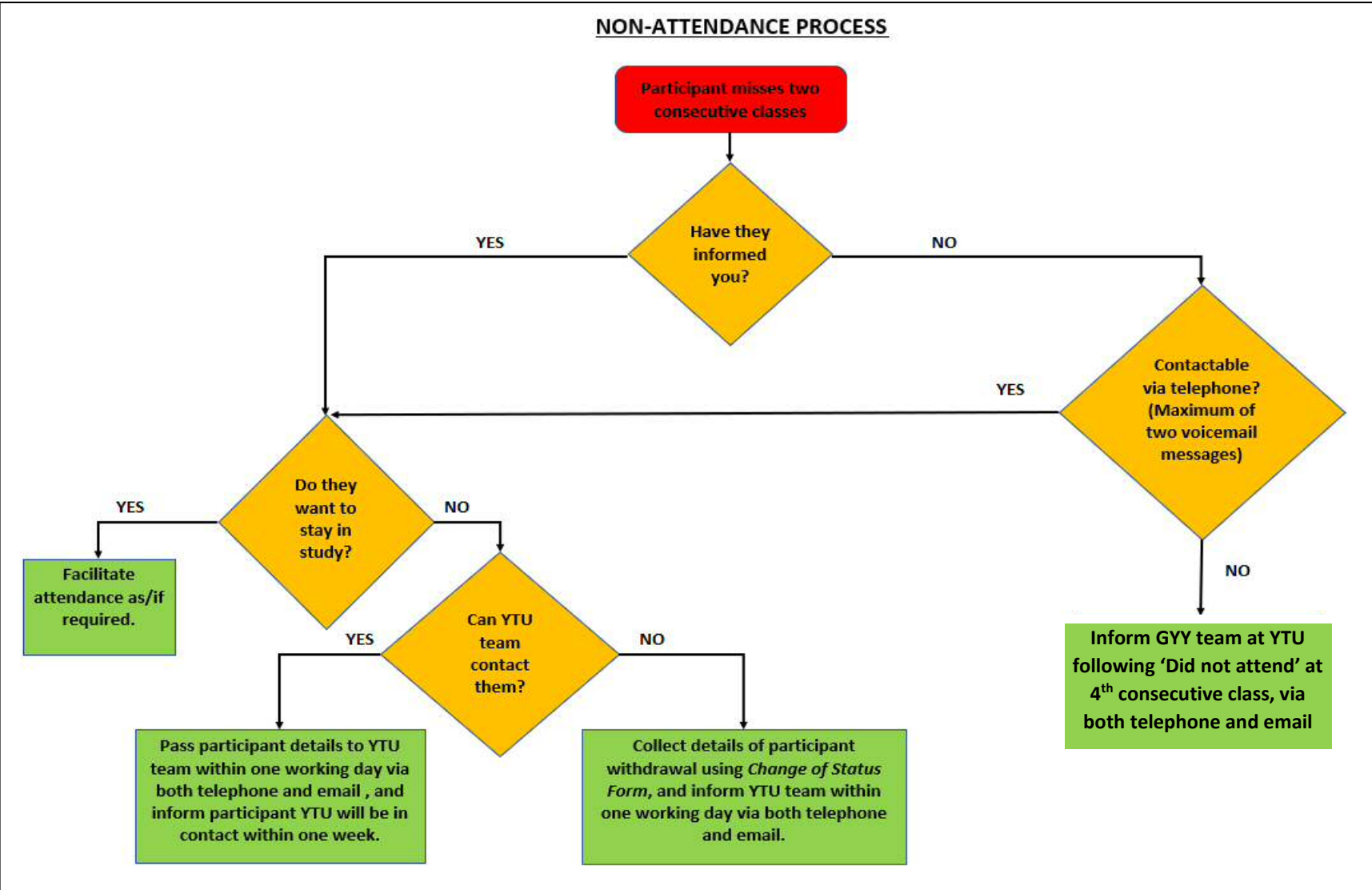


Figure 2. Process for dealing with participant non-attendance

4.5 Completing trial documentation

All trials involve the use of trial-specific documents, to ensure the ethical and standardised recording of our participant details and trial processes.

While the majority of GYY documents are completed by the Trial Management team at YTU, there are some mandatory and optional documents associated with your role. Please refer to **Table 2** and **Appendices** for these documents and exemplars of their associated reporting procedures.

Table 2. GYY documentation for yoga teachers

Documentation	Purpose	Information and Exemplar	Reporting Process
Mandatory			
Class Attendance Register	Recording weekly participant attendance, reasons for non-attendance, and related follow-on actions required.	Appendix 2	Return to GYY trial management team at YTU after each class, via the University of York's DropOff Service (See Section 6.1.2).
Class Participant Details and Reference Class List	Reference copy of participant contact details and weekly class attendance.	Appendix 3	For your reference only, for tracking participant attendance and potential consecutive class non-attendance.
Invoices (including receipts)	Reimbursement of trial-related expenses	Refer to your Yoga Teacher Contract	Return to the GYY trial management team at YTU via the University of York's DropOff Service at the specified times stated in your Yoga Teacher Contract
As needed			
Adverse Event Form	A reference document, for collecting relevant information to pass on to the trials team.	Appendix 5; Chapter 7; Figure 4.	Contact GYY trial management team at YTU via telephone or email within one working day of event notification, to advise you have participant information to report.
Change of Status Form	1. Participant informs you directly of their trial withdrawal and declines contact with the trial management team; 2. You are informed directly of a participant death and asked to pass the information to the trial management team.	Appendix 6; Chapter 4.4; Chapter 8; Figure 5.	Contact GYY trial management team at YTU via telephone or email within one working day of event notification, to advise you have participant information to report.

4.6 Quality assurance

To further reduce bias within a trial, it is important to ensure interventions are delivered consistently, and in line with the trial's protocol, across all sites and teachers. This process is known as quality assurance (QA), and will be carried out by the GYY Yoga Supervisors, Jenny Howsam and Laura Bissell.

To ensure consistency in the content of the 12-week yoga programme, each yoga teacher is required to submit their 12 class plans to Jenny Howsam for pre-approval. Plans are required at least two weeks before the first class is due for delivery, to allow time for any requested amendments to be made.

To ensure the GYY classes are delivered and recorded in accordance with the GYY teacher training programme and GYY Trial guidelines, each yoga teacher will undergo a QA observation of one of their classes by one of the GYY Yoga Supervisors. These observations will be organised with you in advance.

4.7 Process evaluation interviews and observations

Embedded within the GYY trial is a process evaluation, investigating the determinants of implementation, intervention experiences, and optimal strategies for embedding and normalising the yoga intervention for roll-out in the wider community.

As part of this evaluation, we would like to better understand your experiences of delivering the GYY programme both within the context of a randomised controlled trial, and within the context of a multimorbid population. For this, a representative selection of teachers from across all the trial sites will be invited to take part in interviews and/or a class observation with a member of the process evaluation team (Lesley Ward or Tim Rapley).

Please note: Participation in the process evaluation is not a compulsory part of your GYY teacher responsibilities, and no interviews or observations will occur without your written informed consent. Those selected to take part will be provided with full information regarding the process evaluation, to inform their decision.

Chapter 5. Delivering the GYY yoga programme (Intervention)

The GYY trial is being delivered across multiple sites within the UK, by several GYY-trained yoga teachers. To minimise any site-related bias, we have introduced some basic standardised measures for the delivery of the trial. These measures are outlined below and will be further discussed at the Training Day.

5.1 Standardised class structure

Table 3 outlines the standardised structure and content of a GYY class to be delivered in the context of the research trial. The listed content enables a **minimum** level of standardisation in both trial reporting processes and yoga content across all study sites and yoga teachers.

Note: Yoga teachers are to maintain visual contact with the participants during all segments of the class, including relaxation, to oversee the safety of the participants during their yoga practice.

Table 3. Standardised timing and content of a GYY research class

Duration	Segment	Content
~ 5 minutes	'Housekeeping'	<ul style="list-style-type: none"> • Complete class register • Ask how participants are feeling today • Specifically address any health issues since the previous class, to identify potential adverse events • Specifically address any home practice issues
~ 5 minutes	Centring	<ul style="list-style-type: none"> • Introduce specific practices for today's class: Theme (optional); focus asana/s (compulsory). • Basic breathing or other focussing activity
30 - 35 minutes	Extended warm up/mobilisation, preparatory postures	<ul style="list-style-type: none"> • On weeks that a new home practice sheet is introduced (Weeks 1, 4, 7, and 10) tailor the class to cover the contents of the sheet. • Incorporate minimum prop set (1 squishy ball; 1 beanbag; 1 light resistance band; 1 scarf) into asana and dharana activities
10 - 15 minutes	Focus asana(s) and restorative activities	
5 - 10 minutes	Breathing practice	<ul style="list-style-type: none"> • Incorporate practices suitable for beginners, e.g. basic breathing practices such as abdominal breathing. • Avoid breath-retention practices.
5 - 10 minutes	Meditation, relaxation	<ul style="list-style-type: none"> • Incorporate practices suitable for beginners • Avoid explicit Sanskrit manta beyond 'seed sounds'.
15 - 30 minutes	Social time	<ul style="list-style-type: none"> • Opportunity for participant interaction and building of social networks, hosted by the yoga teacher. • Provide general yoga advice if asked • Provision of medically related advice is not appropriate

5.2 Exemplar blurb for addressing adverse events in Housekeeping' segment

An important part of the GYY research trial is monitoring the safety of our older adult participants when they are engaging in their group and home practice yoga sessions. To ensure we capture any safety issues, we require your assistance in identifying potential adverse events.

The following simple text is suggested for enquiring during Housekeeping if participants have experienced any health events that may qualify as a reportable adverse event:

“How has everyone been feeling in the last week after your yoga class or home practice? Has anyone noticed any health issues or aches that they think might be related to doing their yoga practice?”

If you identify any potential safety issues that you think may qualify as a reportable adverse event, please collect relevant details from the participant at the end of the class social time, or privately at the appropriate time, and forward to the GYY research team at YTU, as per the instructions in Chapter 6.3 Reporting adverse events.

5.3 Standardised equipment for asana and dharana activities

We will provide a standard set of props for every trial participant. For face-to-face courses, the props will be sent to you; for on-line courses the props will be sent directly to each participant. The props chosen are considered safe to incorporate into the on-line delivery of the trial classes. For the purposes of delivery of all GYY classes, please limit prop use to these five items only:

- 1 foam block
- 1 ball
- 1 beanbag
- 1 light resistance band
- 1 scarf

In addition, please advise each participant to have access to the following items for their comfort during class:

- Cushion
- Blanket or shawl to keep warm during relaxation.

5.4 Pre-course 1:1 session

5.4.1 For face to face yoga classes

Each teacher will arrange a 1:1 session with each of their participants prior to the first of the 12 group classes. Yoga teachers will be paid for these sessions in addition to their 12 weekly classes. Please note that these meetings **may be held by phone for face to face classes** or via Zoom. The following checklist of items are to be discussed:

- Confirm with participant they have received their yoga randomisation letter from GYY Trials Team at YTU
 - If participant hasn't received their Randomisation Letter please contact the GYY Trials Team ASAP to let them know (gyy-trial@york.ac.uk)
- Address any applicable health issues the participant has indicated on the ***BWY Student Health Questionnaire for GP-Referred GYY students*** they returned to you, which may impact class participation

- If the participant has indicated they have a joint replacement(s) please record the site of the replacement on the form if they have not done so
- Double check the emergency contact name and phone number
- ☐ Provide the participant with an overview of what they need to bring/prepare for each class:
 - Supplied props
 - Cushion (or thick book for under feet, if required) and a blanket or shawl
 - What clothing the participant should wear
 - Home practice sheets
- ☐ Explain to the participant about the social time after class
 - Encourage them to stay for a chat and cup of tea, but clarify this is optional
 - Suggest they might like to bring their own cup and plate
- ☐ Explain how they should contact you if they cannot make it to a session

5.4.2 For on-line yoga classes

To minimise any pragmatic issues our participants may have with joining our on-line yoga classes, a 30 minute 1:1 session is required. Yoga teachers will be paid for delivering these sessions in addition to their 12 weekly classes.

Each teacher will arrange an **individual** 30-minute Zoom meeting with each of their participants prior to the first of the 12 group classes. Please note that these meetings **must be held via Zoom** and not by telephone. This will enable you to ensure that the participant can use Zoom and set up their device so they can see you and you can see them in order to provide supervision during classes. The following checklist of items are to be discussed:

- ☐ Confirm with participant they have received their yoga randomisation letter from GYY Trials Team at YTU
 - If participant hasn't received their Randomisation Letter please contact the GYY Trials Team ASAP to let them know (gyy-trial@york.ac.uk)
- ☐ Confirm with participant they have received their props package (with home practice sheets)
 - If participant hasn't received their props package please contact the GYY Trials Team ASAP to let them know (gyy-trial@york.ac.uk)
- ☐ Discuss what device(s) the participant will be using for the sessions so that you can check where the navigational tools are (start video, mute/unmute, gallery view/speaker view, chat feature) to help with your facilitation at the sessions
- ☐ Talk participant through **your particular process** for the participant to receive and connect/re-connect (in event of problems) to the zoom link
 - Refer the participant to the Class Information Sheet they have been sent
- ☐ Visually assess the suitability of the participant's chair and surrounding environment for taking part in your yoga class e.g., distracting back-lighting; any visible trip hazards surrounding the chair such as electrical cords.
- ☐ Talk the participant through speaker view/gallery view and the positioning of their chair to ensure you will have a full visual of the participant during the yoga classes
- ☐ Address any applicable health issues the participant has indicated on the **BWY Student Health Questionnaire for GP-Referred GYY students** they returned to you, which may impact class participation

- If the participant has indicated they have a joint replacement(s) please record the site of the replacement on the form if they have not done so
- Double check the emergency contact name and phone number
- ☐ If the participant has a history of falls, mobility or frailty issues, check to see if there is a relative or friend who could be in the room to assist with sit to stand transitions.
 - If not, find out if they wear a medical alert/personal alarm and remind them to have it on during class
- ☐ Provide the participant with an overview of what they need to bring/prepare for each class:
 - Supplied props
 - Cushion (or thick book for under feet, if required) and a blanket or shawl
 - What clothing the participant should wear
 - Home practice sheets
 - Prepare tea-making facilities in advance, so they can quickly make a cup of tea to join in the social time after class
- ☐ Explain to the participant about the social time after class
 - Encourage them to stay on for a chat and cup of tea, but clarify this is optional
- ☐ Explain how they should contact you if they are having problems logging in to Zoom or cannot make it to a session

5.5 Before each on-line class

You need to send an email to all participants reminding them about the class and including the Zoom link clearly highlighted so all they have to do is click on it.

On the day, we highly recommend you activate the Zoom link and encourage participants to join 10-15 minutes before the beginning of the yoga class. This will enable any technical issues to be dealt with before the start of the class. It will also allow participants a little time to socialise and chat with each other before they are asked to mute their microphones when the actual class begins. To keep things as simple as possible for participants, please avoid using the 'waiting room' function; this also avoids distractions when a participant loses their connection during a class and is trying to re-join.

Switching to 'speaker view' when everyone but the teacher is muted will allow participants to see the teacher better. Teacher to use 'gallery view' and ask the participants for 'thumbs up' or 'thumbs down' in answer to the teacher's questions. Participants can 'un-mute' and switch to 'gallery view' at the end of lesson before social time. *[Recommended reading: Dan Levy, Teaching effectively with Zoom; Madison Salters, Introduction to teaching with Zoom.]*

5.6 Social time after class

Please provide a **minimum of 15 minutes for social time** at the end of each class and encourage participants to stay on for a chat and a cup of tea if they would like to. This applies equally to face-to-face and on-line classes.

Social time is hosted by you, the yoga teacher. This space after class provides an important opportunity for participant interaction and the building of their social networks; as such, it is important for the conversation to be more general rather than yoga-based.

You may provide general yoga advice to the participants if directly asked. However, if participants ask you for medically-related advice please inform them you are not able to provide that in your role as a yoga teacher on this trial, and suggest they see their GP or appropriate medical professional if necessary.

5.7 Home Practice

Home practice is an integral part of the yoga intervention delivered in our trial. In addition to attending the 12 weekly yoga classes, participants are encouraged to practice at home on non-class days. For courses delivered face-to-face, home practice sheets should be handed out at weeks 1, 4, 7 and 10. On-line Yoga participants will be provided with the four home practice sheets when they receive their set of props. Please ensure participants have their sheets to hand at each class, to refer to if needed.

To ensure a **minimum level** of home practice standardisation across all study sites and yoga teachers, please adhere to the following home practice guidelines:

- Specifically enquire about home practice during the ‘Housekeeping’ segment at the beginning of the class and address any home practice issues that may arise.
- Go through each new home practice sheet on the week it is first introduced (Weeks 1, 4, 7, and 10). Specifically, give adaptations/modifications for each practice/asana as appropriate to support a participant’s individual home practice.
- On the interim weeks (Weeks 2, 3, 5, 6, 8, 9, 11, and 12) please address home practice in the ‘Housekeeping’ section of class and review the home practice sheets in accordance with participants’ needs where necessary.
- No other yoga practice handouts are to be given to participants during the 12-week course.

5.8 Non-trial activities during the 12-week intervention period

We understand that many of the yoga teachers delivering the GYY trial intervention also have their own private yoga businesses, teaching community-based yoga classes. To clarify the boundaries of our GYY trial participants’ involvement in a teacher’s private yoga community, we offer the following guidance:

- You are welcome to discuss the GYY trial and your involvement with your colleagues and students.
- You are welcome to invite your GYY trial participants to join in any socially-related activities you are running with your non-trial community yoga classes (for example, Christmas raffles)
- GYY trial participants are not to be involved in any non-trial workshops or activities you are running which would provide extra yoga instruction during the 12-week intervention period. This is to ensure that the amount and type of yoga our participants receive during the intervention is consistent across all study sites.
- Photos or videos of our GYY trial participants during the trial classes are not permitted, as we do not have research ethics approval or participant informed consent for this.

5.9 Provision of classes following completion of the 12-week intervention period

Our GYY yoga participants may choose to continue with yoga classes following their completion of the 12-week intervention period. To assist with this, at Week 11 we will provide them with a list of age-appropriate yoga classes, both locally and accessible on-line.

We value your local knowledge in helping to develop this trial resource, and the GYY Trials Team at YTU will contact you to ask for your input into this document. In addition to your existing or upcoming classes, you are welcome to suggest any other age-appropriate community classes you consider suitable for our trial population.

Chapter 6. Data protection

Your involvement in the GYY Trial will include the receipt, storage, and delivery of participant-identifying information. To ensure the secure handling of participant information, please read and adhere to:

- Your contract with the University of York
- BWY Data Protection Legislation – A guide for yoga teachers
 - **Note:** For Point 4, Subject Access Request and Point 6, Data Breaches, follow the instructions in your contract with University of York.
- The University of York Information Security Policy:
<https://www.york.ac.uk/about/departments/support-and-admin/information-services/information-policy/index/information-security-policy/#tab-1>
- Data Protection guidelines specific to the GYY trial, as outlined in this Chapter.

6.1 Data transfer – Electronic

6.1.1 Receiving participant information from YTU

Around 1-3 weeks before the start date of your yoga class, YTU will send you the following forms electronically via the University of York's Secure DropOff Service:

- A 'Class Participants Details' form containing participant names, phone numbers, email addresses, contact time preferences, and weekly class attendance
- Twelve anonymised 'Class Register' forms

The DropOff service can be accessed at <https://www.york.ac.uk/it-services/services/dropoff/>. Please refer to the DropOff instructions provided by YTU for further guidance on using this service.

Forms containing participant-identifying information will be protected with a password that YTU will provide to you separately. The password you receive will be unique to you and should not be shared with anyone else.

6.1.2 Returning class registers to YTU

Class registers will not contain any participant-identifying information, they will be pre-populated with only the participants' initials when you receive them. Please **do not** write the participants' names on the register.

Please return each register individually, on a weekly basis. This enables the trial team to monitor class attendance and identify any patterns of non-attendance over the trial sites.

Registers are to be returned electronically via the University of York's Secure DropOff Service, together with any receipts and/or invoices. We suggest keeping a copy of these documents for your reference.

6.1.3 Emailing YTU regarding a participant

If you need to discuss a participant with us via email, please could you use the participant's initials only in the email and no other personal details (i.e., no full name, phone numbers, address, email

address) for data protection purposes. This includes not copying us in any email discussions with the participant. If you need to provide us with any updates to participant personal details etc., please can this either be done over the phone with us or be sent password protected via the DropOff service. Alternatively, you could ask the participant to provide the information to us directly or we can contact the participant to obtain the updated information from them.

6.2 Data transfer of participant's health information

Participants will be sent a copy of the **BWY Health Questionnaire (Appendix 4)** and a free post envelope, and asked to complete and post the questionnaire to you for discussion at the 1:1 session if attending on-line classes. This questionnaire is for your use only - it is not research data and will not be used by the trial team. The questionnaire will include the participant's name, contact details, emergency contact details, health information and the BWY disclaimer for on-line participation. They can indicate if they give permission for future contact and permission to share their information with another yoga teacher who might need to cover your class.

6.3 Data security – Paper documents

To protect our participants' identity and sensitive health information, it is essential we ensure all paper documents, such as the **BWY Health Questionnaire**, are securely stored at all times, both at home and in the yoga venues. Please follow these procedures to ensure secure storage of paper documents:

- When in the community:
 - Carry only the documents you need
 - Do not leave documents unattended e.g. do not leave in a locked car or yoga room
- At home:
 - Keep documents in a locked drawer and keep the key elsewhere in a secure place
 - Don't leave documents on the side where someone can see them

6.4 Data security – Encryption of electronic devices storing participant data

During the GYY trial you may choose to store data and/or communicate with the participant via electronic devices (e.g. mobile phone, tablets, computer) and electronic platforms (e.g. text messages, WhatsApp, emails).

Examples of GYY-related data you might store or use electronically include:

- Research data:
 - Class Participant Details form
- Non-research data:
 - BWY Health Questionnaire
 - Participant's emergency contact details (Name; telephone number; email address)
 - Emails to and from participant
 - Texts to and from participant

IMPORTANT: the University of York requires that any device that holds sensitive or confidential information is encrypted. They have provided the following step by step instructions for device encryption using freely accessible software: <https://www.york.ac.uk/it-services/security/encryption/>

If you require further assistance with encrypting your devices, please contact the GYY trial management team at YTU.

6.5 Data security – Protecting electronic data

IN ADDITION TO encryption of your devices, you must ensure the data on your devices is protected. Full information for secure storage of electronic data can be found on the University of York’s IT security information site: <https://www.york.ac.uk/it-services/security/>

Examples of electronic data protection include:

- Password protection of electronic device (e.g. mobile phone, computer, laptop)
- Password protection of data source (e.g. Word documents)
- Separate user log-ins for shared electronic devices
- Not leaving portable electronic devices unattended (e.g. mobile phone; laptop), even if car or yoga venue is locked
- Not sharing your passwords with anyone else
- Logout of device when not in use
- Consider activating ‘Find my device’ if this is an option on your device.
- Consider activating ‘Remote wipe’ if this is an option on your device.

6.5.1 Email security

To ensure your emails are secure:

- Avoid using a shared email account (e.g. family email)
- Make sure no one else knows your email password
- Log out of your email account when it is not in use

BWY guidelines suggest including an email disclaimer at the end of your emails. The disclaimer below is used by staff at the University of York, which you are free to copy:

“This email and its attachments may be confidential and are intended solely for the use of the intended recipient. If you are not the intended recipient of this email and its attachments, you must take no action based upon them, nor must you copy or show them to anyone. Please contact the sender if you believe you have received this email in error.”

6.6 Protecting hardware

To protect your electronic devices (computers, laptops, tablets) from viruses and malware it is important to install and regularly update anti-virus software and a Firewall. This will help to protect your devices against hackers, certain kinds of malware, and other malicious networks. Further information on virus and malware protection can be found here: <https://www.york.ac.uk/it-services/security/virus/> Additional information is provided below.

6.6.1 Anti-virus software

On the link above, go to the section on 'Unmanaged PCs and personal devices' for guidelines on anti-virus software for your computer type. Ensure that anti-virus software is up to date and running.

6.6.2 Using a Firewall

Some anti-virus packages may include a firewall for you to use, but you may need to switch this option on. Windows and Mac OS X come with a firewall pre-installed. Links on the above web site provide instructions for turning on the Firewall. <https://www.york.ac.uk/it-services/security/network/>

6.6.3 Keeping your computer up to date

It is important to keep your computer software up to date to minimise the risk of malware infection or security breach. Software updates often include security patches, bug fixes and new features:

<https://www.york.ac.uk/it-services/security/update/>

6.6.4 Being vigilant of file sources

One of the easiest ways to keep out a virus or hacker is to not invite them in. Be aware of the following when opening documents or downloading software:

- Never open attachments unless from a trusted source
- Never download software unless from a trusted source
- If someone sends you a link in an email, hover the mouse over the link to see if you are being redirected to another site

6.7 Data breaches

There are three levels at which participant data may be breached: suspected, actual or 'near miss'. If you are aware **of any level** of data breach, the following action is required:

- Notify the trial management team at YTU and Jenny Howsam within **24 hours**.
- The University of York, as the Data Controller, will then inform the Information Commissioner's Office (ICO) within 72 hours of an actual data breach unless the breach is unlikely to result in a risk to the rights and freedoms of natural persons.

6.8 Data subject requests

You may not give out any personal participant data without the consent of the University of York.

If you are contacted by a participant or by the Information Commissioners Office to provide any participant data in relation to the GYY Trial please refer the person directly to the GYY trial management team at YTU.

6.9 Data destruction

6.9.1 Non-trial data

In the context of the GYY Trial, non-trial data is limited solely to data collected on the **BWY Health Questionnaire**.

The following statement from BWY (BWY Data Protection & Legislation Guide Dec 2018, point 9, page 3) applies to the destruction of non-trial data: *"Personal data should only be kept for the time it still serves a purpose. It is fine to keep some of their data, for example in case you need to contest a future legal issue, so with this in mind please keep your data for 7 years."*

6.9.2 Trial data

All participant data that is not from the BWY Health Questionnaire is considered GYY trial data and must be securely destroyed or removed from your devices following completion of the 12-week yoga course. YTU will advise you of the timeline for data destruction following completion of the GYY trial.

Data is to be destroyed as follows:

- Paper documents supplied by York Trials Unit are to be shredded
- Electronic files are to be deleted from all devices

Chapter 7. Adverse events

You are not expected to deal with any major problems that participants may incur as a result of their trial involvement. However, you may be the first point of contact for a participant or their family member/support person to report a trial-related health or safety event (known as an adverse event).

This chapter describes what constitutes an adverse event in the context of the GYY trial, which adverse events are reportable, how to report them to the GYY trial management team at YTU in an efficient and timely manner, and possible scenarios we may see in the yoga classes.

PLEASE NOTE: The procedures outlined in this chapter are in addition to, not in place of, current BWY reporting protocols which are available in the members section of the BWY website.

7.1 What is an adverse event

An **Adverse Event** (AE) is any untoward medical occurrence a participant may experience. This could include any unfavourable clinical sign or symptom, any new illness or disease, or the deterioration of an existing disease or illness.

If an adverse event meets any of the five following criteria, it is escalated in severity and called a **Serious Adverse Event** (SAE):

- Results in death
- Is life threatening (The participant was at risk of death at the time of the event. It does not refer to an event which hypothetically might have caused death if it were more severe).
- Requires in-patient hospitalisation or prolongation of existing hospitalisation (A planned hospitalisation for a pre-existing condition is not considered to be a serious adverse event)
- Results in persistent or significant disability or incapacity
- Consists of a congenital anomaly or birth defect. Other 'important medical events' may also be considered serious if they jeopardise the participant or require an intervention to prevent one of the aforementioned consequences.

Other 'important medical events' may also be considered serious if they jeopardise the participant or require an intervention to prevent one of the above consequences.

If you have any additional concerns regarding immediate or potential hazards to the health or safety of trial participants which are not detailed below, please contact the GYY trial management team at YTU so we can improve our services accordingly.

7.2 What adverse events are reportable

The GYY trial is considered a low-risk research study. However, given the participant population and physical nature of the yoga programme, certain AEs/SAEs are to be **expected**. For example, transient muscle soreness, falls, and musculoskeletal injury are possible (although unlikely) consequences of yoga; while acute illness resulting in hospitalisation, medical instability, and death are not uncommon in older, multimorbid adults.

As such, for the GYY study we will record and report the following:

- Only those non-serious AEs that are deemed to be **related** to taking part in the trial or intervention (both GYY classes and home practice). Examples include, but are not limited to:
 - Delayed onset muscle soreness which fails to resolve 72 hours following class or home practice
 - Substantial increases in pre-existing pain which fails to resolve 72 hours following class or home practice
 - Development of new musculoskeletal pain which fails to resolve 72 hours following class or home practice (e.g. acute neck pain)
 - Injuries sustained as a result of an accident incurred travelling to or from a yoga class
- All** SAEs will be reported

7.3 Reporting adverse events

In addition to your usual reporting process of adverse events required by BWY, our trial has developed a **time-critical** reporting process, to enable swift identification of unanticipated issues which may compromise participant safety. **Events must be reported via telephone AND email either on the day you were made aware of them or, if that is not possible, on the next working day.**

A simplified outline of the reporting procedure is given in **Figure 3**. If in doubt, always err on the side of caution. If you are unsure whether a participant's health issue constitutes a reportable event, please contact the GYY trial management team at YTU for further advice.

Documentation of all AEs/SAEs will be carried out by the GYY trial management team at YTU. Your role is to inform the team that such an event has occurred. To aid this, it is useful to familiarise yourself with the **Adverse Event reporting form** these events are recorded on (**Appendix 5**).

Report any AEs to the GYY trial management team at YTU using the following two-step process:

- i. Firstly, telephone the GYY trial management team using the Emergency-only telephone number (0800 9154992). If there is no answer, please leave a number and a time to telephone you back. For data protection reasons, please do not leave the participant's name in the message.
- ii. Secondly, follow this telephone call with an email to the trial team (gyy-trial@york.ac.uk), marking the email as 'High Importance'.
 - If you talked to a GYY team member in Step i., then write the email as a brief confirmation of your telephone conversation, noting the participant's initials, name

of the GYY team member you spoke with, and date and time of the telephone conversation.

- If you had left a voicemail in Step i., then repeat the information again in the email, and give a suitable time for the GYY team to contact you for further details. For data protection reasons, please do not write the participant's name in the message.

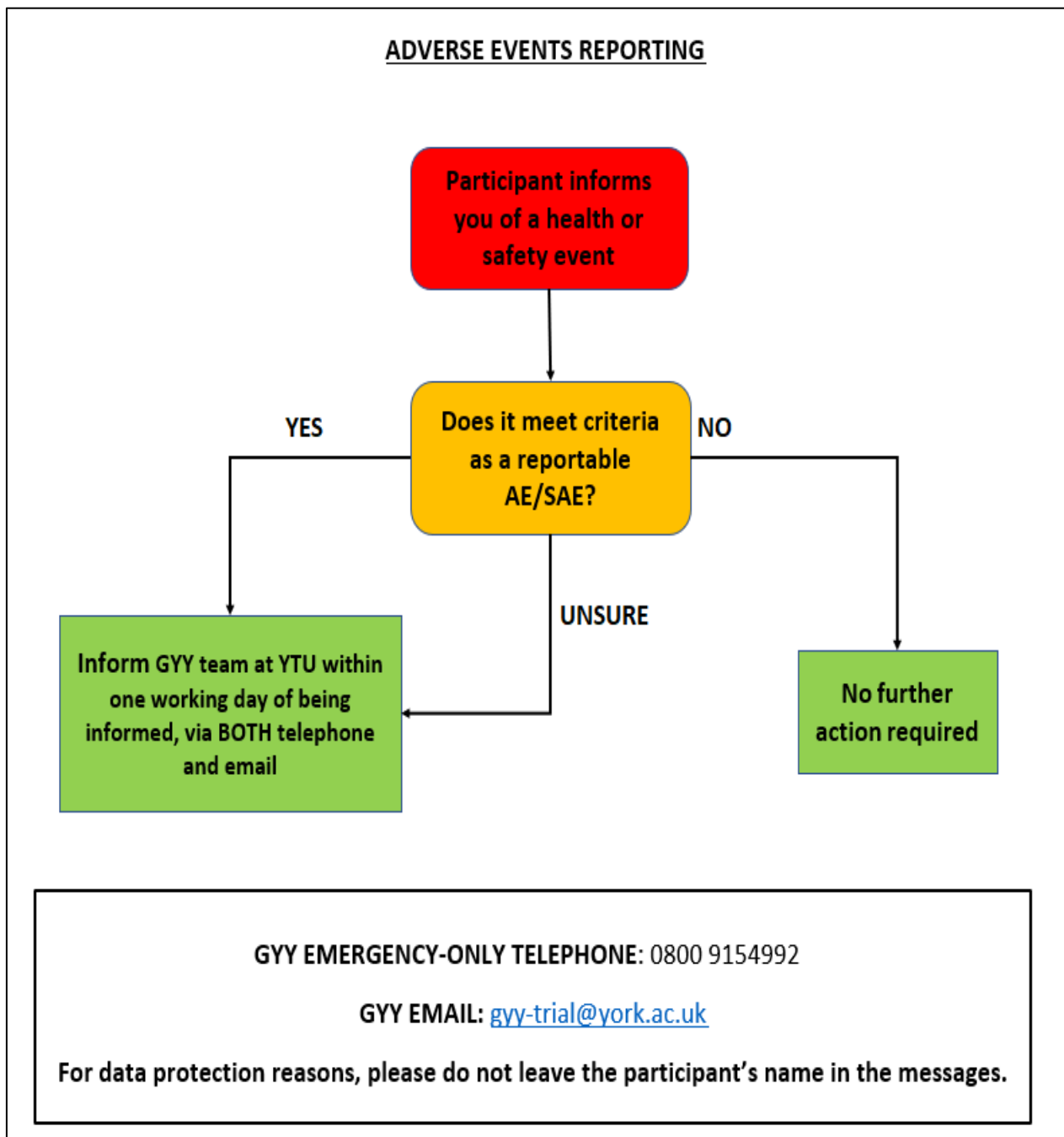


Figure 3. Adverse events reporting process

7.4 Possible scenarios for adverse events

In the case of a medical event occurring during an on-line yoga class:

- If the event is potentially life threatening, call 999 immediately and pass on the participant's location details to the emergency services
- If the event needs urgent medical attention but is not life-threatening call NHS 111 for advice
- If the event does not need urgent medical attention, advise the participant to access their GP or local minor injury service, or to call NHS 111 for advice
- Call the participant's emergency contact if you consider this applicable
- Follow the trial's adverse event reporting procedure, as described in section 7.3

In the context of the GYY trial, if a participant experiences an AE it may be unrelated to their trial participation, related to class practice, or related to home practice.

It is sometimes difficult to decide the seriousness or relatedness of an AE. Below are some possible scenarios to assist you in deciding whether an AE has occurred, and how to deal with possible situations you may face.

Scenario 1 - What happens if a participant reports experiencing pain during a yoga class?

Mild, transient increases in pain are to be expected during or following a yoga class. This may be related to using muscles in a different or more intense way than usual resulting in delayed-onset-muscle-soreness (DOMS), it may be related to a co-morbidity (e.g. knee osteoarthritis), or it may be an indication of a more serious event, such as a heart condition.

Therefore, it is important to assess these symptoms in the context of the individual and their associated health conditions:

- Was the pain present prior to the class beginning or did it present during class?
- Is the pain associated with a pre-existing condition? (e.g. rheumatoid arthritis) If so, how severe is the pain compared to their usual level?
- Is the pain likely to be associated with a serious, acute, event (e.g. angina, heart attack)?

When assessing the situation:

- Ask the participant to stop and rest
- Provide appropriate reassurance
- Explain that the yoga movements may be uncomfortable to begin with as their joints and muscles need to get used to being stretched and strengthened
- If their pain settles when resting, re-engage with the yoga movements but at a reduced level
- If their pain worsens, stop the yoga movements, and ask the participant to monitor their pain levels over the next couple of days

- If you consider the pain is related to a more serious condition, call an ambulance or their emergency contact as applicable
- If their pain lasts longer than 72 hours ask them to contact you.
- If you consider the event meets the criteria for a reportable AE or SAE, follow the appropriate reporting procedures outlined above.

Scenario 2 - What happens if a participant becomes unwell during a yoga class?

- If a participant reports any of the usual signs which may occur during exercise, such as feeling hot, muscle soreness, feeling tired, or transient dizziness, ask them to rest for 5-10 minutes. If the signs do not persist or progress, no further action is required, and the participant may re-engage with the class.
- If a participant reports feeling ill, ask them to stop the class, and advise them to contact their GP on their return home if applicable.
- Call their emergency contact if you consider this applicable, for example if you think they need assistance in getting home.
- If a participant becomes seriously unwell, an ambulance should be called.
- If you consider the event meets the criteria for a reportable AE or SAE, follow the appropriate reporting procedures outlined above.

Scenario 3 - What happens if a participant falls during an exercise class?

- If a participant trips or stumbles but does not fall, this is not an AE or SAE. Investigate how the incident occurred, as this may indicate an issue with the venue which needs to be resolved, such as loose carpet, or a particular problem for that participant requiring closer supervision, such as vision issues.
- If a participant falls during a class, this would be considered an AE and the appropriate reporting procedures should be followed as outlined above.
- If the participant sustains injuries consistent with an SAE or is admitted to hospital, this should be reported as an SAE and the appropriate time-critical reporting procedures should be followed as outlined above.

Scenario 4 - What happens if a participant becomes unwell outside of an exercise class?

- Regardless of the seriousness of the health event, if it is clearly unrelated to the yoga class or home practice, it should not be reported as an AE or SAE; for example, if a participant was hospitalised with a viral infection.
- If the health event is either an exacerbation of a pre-existing condition, e.g. angina, or a new symptom, e.g. chest pain, which might have been brought on by exercise, this should be considered a reportable AE or SAE, and the appropriate reporting procedures as outlined above.

Chapter 8. Withdrawals, and deaths

In your role as the GYY yoga teacher you may be the first point of contact for information regarding a participant withdrawal or death. These events must be reported to the GYY trial management team at YTU in an efficient and timely manner. The reporting process for notifying YTU of these events is outlined below and in Figure 4.

8.1 Participant withdrawals

Participants may withdraw from the GYY Trial at any stage. They do not need to explain their reason, and their withdrawal will not impact their usual care or treatment. A participant's GP may also request that a participant be withdrawn for clinical reasons, such as a sudden worsening of health.

Participants who withdraw from the study will not be replaced, and the GYY trial management team at YTU will notify you if a participant will no longer be attending your classes.

In some instances, a participant's reason for withdrawal may relate to miscommunication or concern regarding their trial participation. In our experience, receiving simple reassurance from the teacher or the trial team will often allay their concerns, and the participant may choose to stay in the trial.

The process for dealing with a participant request to withdraw is as follows:

- i. Ask the participant if the GYY trial team at YTU may contact them to process their withdrawal.
 - o If the participant **agrees** to this contact, inform them you will pass their details to the team, who will contact them within the week.
 - o If the participant **declines** this contact, use the **Change of Status form (Appendix 6)** to collect information regarding the participant's withdrawal to pass on to the trial management team on the participant's behalf, and inform the participant they will not be contacted further regarding the trial.
- ii. Telephone the GYY trial management team using the Emergency-only telephone number (0800 9154992) **within one working day** of being informed of the participant withdrawal, advising the team whether the participant has agreed or declined further contact from the team. If no answer, please leave a number and a time to phone you back. For data protection reasons, please do not leave the participant's name in the message.
- iii. Follow-up this telephone call with an email to the trial team (gyy-trial@york.ac.uk), marking the email as 'High Importance'.
 - o If you talked to a GYY team member in Step ii., then write this email as a brief confirmation of your telephone conversation, noting the participant's initials, name of GYY team member you spoke with, and date and time of the telephone conversation.
 - o If you left a voicemail in Step ii., then repeat the information again in the email, and give a suitable time for the GYY team to contact you for further details. For data protection reasons, please do not write the participant's name in the message.

8.2 Participant death

Our trial involves an older age group with chronic health issues. It is important that a participant death is reported immediately, to ensure that we are not contacting the participant's family to investigate class absence, and to investigate if their death was trial-related.

If you are informed that a trial participant has died please contact the GYY Trial Management Team at YTU, following the process outlined in Section 6.3 for reporting adverse events.

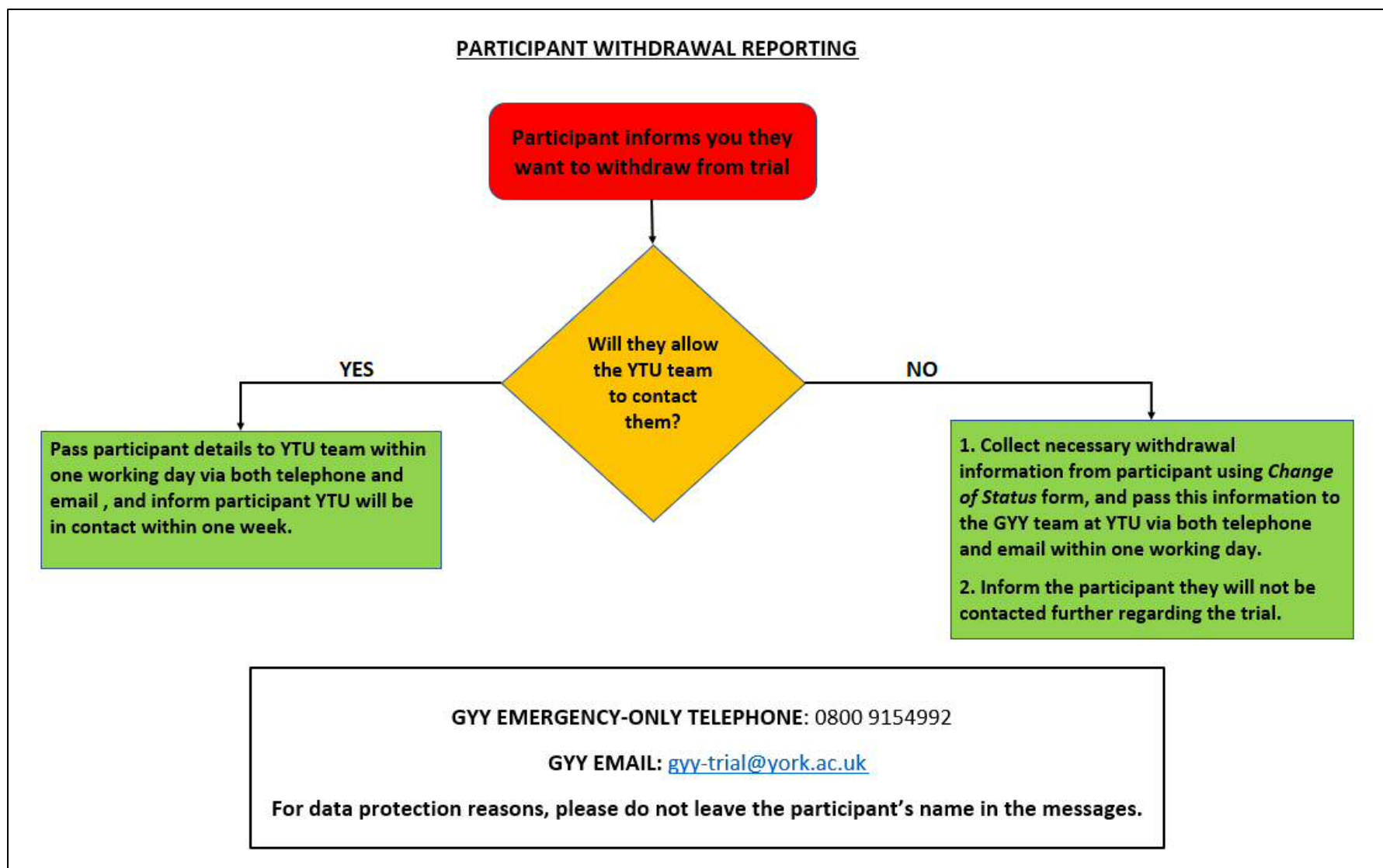


Figure 4. Participant withdrawal reporting

References

- Andronis, L., et al. (2017). "Cost-effectiveness of non-invasive and non-pharmacological interventions for low back pain: a systematic literature review." Applied of Health Economics and Health Policy **15**(2): 173-201.
- Barnett, K., et al. (2012). "Epidemiology of multimorbidity and implications for health care, research, and medical education: a cross-sectional study." Lancet **380**(9836): 37-43.
- Cramer, H., et al. (2017). "Yoga for improving health-related quality of life, mental health and cancer-related symptoms in women diagnosed with breast cancer." Cochrane Database of Systematic Reviews(1): Art. No.: CD010802.
- Cramer, H., et al. (2015). "The safety of yoga: a systematic review and meta-analysis of randomized controlled trials." American journal of epidemiology **182**(4): 281-293.
- Eckardt, M., et al. (2017). "Analysis of health care costs in elderly patients with multiple chronic conditions using a finite mixture of generalized linear models." Health economics **26**(5): 582-599.
- Garvey, J., et al. (2015). "OPTIMAL, an occupational therapy led self-management support programme for people with multimorbidity in primary care: a randomized controlled trial." BMC family practice **16**:59
- Gitlin, L. N., et al. (2006). "A randomized trial of a multicomponent home intervention to reduce functional difficulties in older adults." Journal of the American Geriatrics Society **54**(5): 809-816.
- Goodwin, N., et al. (2014). Providing integrated care for older people with complex needs: lessons from seven international case studies, King's Fund London.
- Gothe, N. P. and E. McAuley (2015). "Yoga is as good as stretching–strengthening exercises in improving functional fitness outcomes: Results from a randomized controlled trial." Journals of Gerontology Series A: Biomedical Sciences and Medical Sciences **71**(3): 406-411.
- Hoffmann, T. C., et al. (2014). "Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide." BMJ **348**:g1687.
- Mangin, D., et al. (2012). "Beyond diagnosis: rising to the multimorbidity challenge." BMJ **344**: e3526.
- McPhail, S. M. (2016). "Multimorbidity in chronic disease: impact on health care resources and costs." Risk management and healthcare policy **9**: 143-156.
- National Institute for Health and Care Excellence (2016). "Multimorbidity: clinical assessment and management." Retrieved 24 September, 2019, from <https://www.nice.org.uk/guidance/ng56>.

NHS (2019). "A guide to yoga." Retrieved 03 October, 2019, from <https://www.nhs.uk/live-well/exercise/guide-to-yoga/>.

Patel, N. K., et al. (2012). "The effects of yoga on physical functioning and health related quality of life in older adults: a systematic review and meta-analysis." Journal of Alternative and Complementary Medicine **18**(10): 902-917.

Salisbury, C., et al. (2011). "Epidemiology and impact of multimorbidity in primary care: a retrospective cohort study." British Journal of General Practice **61**(582): e12-e21.

Smelt, A. F., et al. (2010). "How usual is usual care in pragmatic intervention studies in primary care? An overview of recent trials." British Journal of General Practice **60**(576): e305-e318.

Smith, S. M., et al. (2016). "Interventions for improving outcomes in patients with multimorbidity in primary care and community settings." Cochrane Database of Systematic Reviews(3).

Tew, G. A., et al. (2017). "Adapted yoga to improve physical function and health-related quality of life in physically-inactive older adults: a randomised controlled pilot trial." BMC geriatrics **17:131**

Wieland, L. S., et al. (2017). "Yoga treatment for chronic non-specific low back pain." Cochrane Database of Systematic Reviews(1): Art. No.: CD010671.

Wolff, J. L., et al. (2002). "Prevalence, expenditures, and complications of multiple chronic conditions in the elderly." Archives of internal medicine **162**(20): 2269-2276.

Yang, Z. Y., et al. (2016). "Yoga for asthma." Cochrane Database of Systematic Reviews(4): Art. No.: CD010346.

Youkhana, S., et al. (2015). "Yoga-based exercise improves balance and mobility in people aged 60 and over: a systematic review and meta-analysis." Age and ageing **45**(1): 21-29.

Appendices

The appendices below provide exemplars of trial documents which you may be required to complete or refer to in your role as a GYY Trial Yoga Teacher.

If you are unsure whether an event should be reported or not, please always act on the side of caution and contact the GYY Trial team at YTU for further advice.

Appendix 1. BWY – Risk Assessment Form



The British Wheel of Yoga
25 Jermyn Street
Sleaford, Lincolnshire
NG34 7RU

BWY – Risk Assessment Form

Tutor:	
Day and time of class:	
Venue (including postcode):	
Are the relevant qualifications & certifications up to date?	
BWY Membership & Insurance	
First Aid	

The Venue:

Are premises in a satisfactory state of repair?	
Are accesses, exits, passages and stairways, safe and unobstructed?	
Are you aware of emergency exits in the event of an emergency?	
Have you ensured exits are clearly marked and that there is clear access to doors/ they are not locked?	
Is the space safe, clear, clean and free of obstructions?	
Furniture & equipment stacked safely and away from participants?	
Are evacuation procedures in place?	
Have you identified an assembly point in the event of an emergency or fire?	
Are class aware of fire procedures including escape routes & meeting points?	
If you are using a public building e.g. a school, leisure centre etc., do you know where the nearest fire bell is sited so you can alert others?	
Are fire extinguishers accessible, of correct type & maintained & are you trained to use them?	
Do your attendees know they must not try to extinguish a fire themselves, unless they are an appointed person, and that you must be informed immediately?	
Are the premises accessible to the emergency services?	
Is the floor safe and appropriate for yoga?	
Are the premises heated adequately and is the room well ventilated?	
Have all the venue's electrics been PAT Tested and declared safe?	
Do you have a complete register of all yoga course participants?	
Have all students completed the Health questionnaire?	

In the event of an injury is the following to hand:

First Aid Box	
Incident Report Forms – own, venue and BWY	
Emergency contact numbers	
Do you have access to a phone or mobile in case of emergencies?	

List any risks identified at your venue or as part of your lesson providing full details and the measures you will put in place to reduce any risks e.g.: *Check chairs / other equipment safely stacked/ Check fire access route not blocked – fire doors shut/ Check drinks bottles etc. safely out of way during practice:*

COVID 19 ADDITIONS TO RISK ASSESSMENT

Covid-19 - a guide for tutors:

If you are teaching face to face during covid then you must consult the latest BWY statement on covid protocols to understand the current government guidelines and how they relate to your class. This risk assessment is intended to provide pointers; full details will be in the BWY current covid statement and the “BWY Best Practice Guidance for face to face Teaching during Covid”.

In brief:

- Consult gyms/leisure centres and any venues where you teach to ensure that you adhere to their covid protocols.
- Advise all students not to attend classes if they are/ or think they might be in breach of guidelines (re: return travel, flu like systems etc.)
- It is the responsibility of the venue owner to clean and disinfect the rooms, but it is the responsibility of the teacher to make sure this is done properly.
- Ask students to “scan and check in” on arrival for track and trace.
- Put in place social distancing measures – all mats at least 2m (or 1m if masks worn) apart, in accordance with BWY mat spacing diagram.
- Clean and disinfect floors and surfaces between classes and on a regular basis, clean and sanitize all equipment after use.
- Ensure hand sanitiser is available at the start and end of every class.
- Wash hands on a regular basis (before and after class).
- Ensure room is well ventilated before, after and during class.
- Ask students to bring their own mat/equipment to classes and avoid sharing.
- Avoid hands on adjustments and favour verbal communications instead.

Name (printed):	
Signed:	
Date:	

Appendix 2. Class Attendance Register Example

The Gentle Years Yoga Trial: Class Attendance Register							
Name of Teacher:		Jo Stoggs		Date of Class:	22/04/2021	Week Number:	5/12
Participant initials	Attended class? (Y/N)	If participant did not attend class:			*See Manual Chapters 4, 7 and 8 for further information		
		Were you informed they would not be attending? (Yes, prior to class; Yes, after class; Not informed).	Reason for non-attendance (Sickness; Injury; Surgery; Medical appointment; (if yoga related inform GYY trial team)*; Holiday; Family commitments; Unknown; Other [please state]).	How were you informed? (Telephone; Text message; Email; Face to face; Other [Please state]. Say if you or they initiated the contact).	Do you need to follow-up? (Yes; No; Unsure)*	If yes, which type: (Two week non-attendance; Adverse event; Withdrawal; Other [Please state]).*	
1. GT	Y						
2. CM	Y						
3. LW	Y						
4. LB	Y						
5. JHJ	Y						
6. LAW	N	Yes prior to class	Migraine	They emailed me	No		
7. EB	N	Yes before class	Back pain - not yoga related	They phoned me	No		
8. JR	N	Not told	Unknown	—	Yes	Two weeks in a row non-attendance	
9. ET	Y						
10. FR	N	Yes after class	Other: doesn't want to do it anymore	I rang them	No	Withdrawal - Change of status done	
11. AM	Y						
12. BT	Y						
ADDITIONAL COMMENTS:							
Please return to gyy-trial@york.ac.uk via the University of York's DropOff Service (https://dropoff.york.ac.uk/)							

The Gentle Years Yoga Trial - Reference Class List

Name of Teacher: Josephine Bloggs

Participants Name and Initials	Wk 1	Wk 2	Wk 3	Wk 4	Wk 5	Wk 6	Wk 7	Wk 8	Wk 9	Wk 10	Wk 11	Wk 12
1. GT	✓	✓	✓	✓	✓				×			
2. CM	✓	✓	×	✓	✓							
3. LW	✓	✓	✓	✓	✓							
4. LB	✓	✓	✓	✓	✓							
5. J H-J	×	✓	✓	✓	N							
6. Low	✓	×	✓	✓	N							
7. GB	✓	N	✓	N	N							
8. JR	✓	✓	×	✓	✓							
9. VT	✓	×	✓	✓	N	×	×	×	×	×	×	×
10. FR	✓	✓	✓	×	✓							
11. AM	✓	✓	✓	×	✓							
12. BT	✓	✓	✓	✓	✓							
13.												
14.												
15.												

This register class list is for **your reference only** and does not need to be returned to the York Trials Unit.

If a participant has missed two consecutive classes without notifying you, please contact them as outlined in Section 4.4 (Dealing with Non-attendance) and Figure 2 (Process for dealing with participant non-attendance) of the GYY Research Delivery Manual.

Appendix 4. BWY Health Questionnaire

Please post completed form to your yoga teacher 10 days before your first Gentle Years Yoga session, using the stamped addressed envelope



British Wheel of Yoga – Gentle Years Yoga STUDENT HEALTH QUESTIONNAIRE

Revised 27th August 2020

<i>To be completed by yoga class participants for face to face and remote teaching. All information given will be treated in the strictest confidence and stored in accordance with General Data Protection legislation.</i>			
Name:			
Date of Birth:		Age:	
Address:			
Telephone Number(s):	Home:		
	Mobile:		
Email:			
Emergency contact name:			
Emergency contact telephone number:			
Have you attended a yoga class before? [please answer 'Yes' or 'No']			
If yes, how long have you practised yoga and what style of yoga have you practised?			
Whilst yoga may be practised safely by most people, there are certain conditions that require special attention. Please indicate in the boxes below whether or not you have any of the following medical conditions and then provide further information:			
These conditions require specific modifications to your yoga practice:			
Abdominal disorder or recent surgery		Arthritis (osteo or rheumatoid)	
Unspecified back pain/ problems		Spinal injury	
Joint replacement [specify which joint(s) in space below]		Knee problems	
Hip problems		Shoulder or neck problems	
Heart disorders		High blood pressure	
Low blood pressure		Other (discuss with yoga teacher)	
Further information:			
These conditions may affect your practice and so it will be useful for your yoga teacher to be aware of them:			
Asthma		Diabetes	
Anxiety/depression		Auto-immune disorder (e.g. M.E., M.S., Lupus etc.)	
Epilepsy		Balance affecting disorder	
Respiratory issues		Migraine	
Sensory disorder affecting eyes or ears		Other (discuss with yoga teacher)	
Further information:			

Your GP surgery referred you to the Gentle Years Yoga classes on the basis that you have two or more health conditions to declare. Please tick or X that you have declared all relevant health conditions here →

If you have not declared any health conditions on the preceding page, your yoga teacher cannot give you the appropriate modifications/adjustments that are related to your participation.

Have you had any recent operations (in the last two years)? [please indicate 'Yes' or 'No'. If 'Yes', please provide details.]

Do you have any old injuries that still trouble you? Or any other medical conditions not covered above that might be adversely affected by yoga practice? [please indicate 'Yes' or 'No'. If 'Yes', please provide details.]

Do you participate in any other physical activity, e.g. gym, jogging, swimming, aerobics, cycling, walking or other? [please indicate 'Yes' or 'No'. If 'Yes', please provide details.]

How regularly do you do this/these?

Disclaimer - Please read carefully; your submission of this form will be taken to indicate your acceptance of the following:

Please take care when filling in this questionnaire and check the contents are accurate before you submit it. By submitting the questionnaire, you are confirming that the contents are true and accurate to the best of your knowledge. Please notify your teacher of any changes to your responses in this healthcare questionnaire before participating in classes subsequent to those changes.

Your GP surgery has referred to you be a participant in the Gentle Years Yoga classes. Neither your teacher nor the British Wheel of Yoga are qualified to express an opinion that you are fit to safely participate in any British Wheel of Yoga organised sessions or any British Wheel of Yoga trained teacher's yoga classes. If you have any medical concerns, please talk with your GP or specialist.

If you have any discomfort while practicing yoga, please talk with your yoga teacher. Where possible, your teacher will offer suitable modifications or adjustments and practices to suit different levels of experience and ability.

Before your first class your teacher will be contacting you by email or phone to arrange a one-to-one meeting on Zoom to familiarise you with the procedures and to figure out the best distance between your chair and computer device. Hopefully, your teacher will have received this Health Questionnaire in advance of your one-to-one meeting so that any questions can be answered privately.

Once your online classes start, always follow your teacher's safety instructions and listen to your body. Where a movement is beyond your experience or ability, feels too difficult for you, or you experience any discomfort, please do not continue the movement. Discuss the situation with your teacher.

Name (please print):

Signature *if using a printed out paper copy:*
Otherwise indicate with a tick or X

.....

I confirm my understanding and acceptance of this health questionnaire and its disclaimer:

Date:

General Data Protection Regulations Statement

In order to comply with the General Data Protection Regulations, your teacher only holds information when it is necessary to do so in order to carry out their work, and when you have given your permission. Are you happy for your teacher to retain your contact details and to share information with a substitute teacher if required?

YES / NO

Are you happy for your teacher to send information about relevant updates and events that might be useful to you?

YES / NO

Communication: Bearing in mind that your online yoga classes on 'Zoom' may require link updates by Email and your teacher may need to phone you if there is an emergency cancellation, please indicate your communication preferences.

Means of Communication:	Email YES / NO	Post YES / NO	Telephone YES / NO

Appendix 5. Adverse Events Report Form

Adverse Event REPORT FORM (Page 1 of 2)			
Trial:	Gentle Years Yoga	AE reference number: <i>(YTU use only)</i>	
1. Person making report			
Name:			Assessor ID: <input type="text"/>
Job title/role in study:			
Contact address:			
Email address:			
Contact Telephone No:		Fax number:	
2. Details of study			
Title: Gentle Years Yoga	Name of Chief Investigator:		
3. Details of participant affected by AE			
Participant study ID: <input type="text"/>	DOB: <input type="text"/> / <input type="text"/> / <input type="text"/>		
	<small>day</small>	<small>month</small>	<small>year</small>
4. Details of AE			
Full description of event, including body site, reported signs and symptoms and diagnosis where possible:			
Participant reported severe shoulder pain after last week's class. Still in pain and unable to lift arm properly. Right shoulder/arm.			
Action taken:		*If 'Other', please specify below.	
<input type="checkbox"/> None <input type="checkbox"/> Study treatment interrupted/ halted <input type="checkbox"/> Therapy prescribed/ other likely action <input type="checkbox"/> Discontinued study <input type="checkbox"/> Other*			
Onset Date	Onset Time (if known)	End Date	End Time (if known)
<input type="text"/> / <input type="text"/> / <input type="text"/>	<input type="text"/> : <input type="text"/>	<input type="text"/> / <input type="text"/> / <input type="text"/>	<input type="text"/> : <input type="text"/>
<small>day</small>	<small>hh</small>	<small>day</small>	<small>hh</small>
<small>month</small>	<small>mm</small>	<small>month</small>	<small>mm</small>
<small>year</small>		<small>year</small>	
Presence of event is / was: <input checked="" type="checkbox"/> Continuous <input type="checkbox"/> Intermittent			
Location of Adverse Event (e.g. GYY Yoga Class, Other Yoga Class, Hospital, participant home), please specify below:			
During week 4 yoga class			
5. Outcome			
<input type="checkbox"/> Resolved*	<input type="checkbox"/> Resolved with Sequela †*	<input type="checkbox"/> Died* (give cause and PM details if available)	
<input type="checkbox"/> Ongoing*	<input type="checkbox"/> Ongoing with Sequela †*	<input type="checkbox"/> Ongoing (intermittent)*	
†Sequela refers to a condition which is the consequence of a previous disease, injury, therapy or other trauma; a chronic condition that is a complication following a more acute condition			
*Give details:			
Was the patient withdrawn from the study? <input type="checkbox"/> Yes <input type="checkbox"/> No			

Adverse Event REPORT FORM (Page 2 of 2)

6. Relationship to study treatment and Expectedness (to be completed)		
<input type="checkbox"/> Not related <input type="checkbox"/> Unlikely to be related <input type="checkbox"/> Possibly related* <input checked="" type="checkbox"/> Probably related* <input checked="" type="checkbox"/> Definitely related*	<p>*If possibly, probably or definitely related, was the AE unexpected?</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No <i>Unsure</i></p> <p>(Unexpected means not described in the protocol)</p>	<p>Please complete and return all sections of the follow up report form when further information is available.</p>

Is the event defined as serious? i.e. resulted in death, is/was life threatening required hospitalization, prolonged and ongoing hospitalization, resulted in persistent or significant disability/incapacity, resulted in a congenital anomaly or birth defect.



Yes* *If 'Yes', a Gentle Years Yoga Serious Adverse Event (SAE) Form must be completed

No

I confirm that the contents of this form are accurate and complete

Signature of person completing page: _____		Date: <input type="text"/> / <input type="text"/> / <input type="text"/>
		<small>day month year</small>
Assessor ID: <input type="text"/>		
Print name: _____	Job Title: _____	

Appendix 6. Change of Status Form

	The Gentle Years Yoga Trial Change of Status Form	 <small>The Department of Health Sciences</small>
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Please complete this form if there are any changes in the status of the Gentle Years Yoga participant.

Participant ID:

Date became aware of change in status: / /
day month year

Reason for change in status:

1. Participant has died

A Serious Adverse Event form has been completed: Yes No
If 'No', please ensure one is completed

Date of death: / /
day month year

Information received from:

2. Participant is being withdrawn (please specify level of withdrawal by crossing one box below):

Participant wants to be withdrawn from the intervention but agrees to further follow-up

Participant wants to be withdrawn from follow up only

Participant wants to be fully withdrawn

3. Lost to Follow-up

Please provide further information for change in status:

Date this form was completed: / /
day month year

Details of person completing this form:

Name (Print):

Job Title / Role in study:

Signature:

<small>GY Y Change of Status Form v1.1 06.06.2019</small>	<small>Page 1 of 1</small>	<small>IRAS: 255698 1635506253</small>
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