

Section of the TMF/ ISF	Document Name	Document Version	Document date	Amendment number	Date approved by REC	Reason for change to document
2.1	ATM protocol	13	26-Nov-19	20	07-Jan-20	No cost extension to ensure recruitment target is achieved, new study timelines: - May 2020 - End of recruitment, - October 2020 - End of follow-up, - February 2021 - End of study. Changes to study protocol including - Page 27 section 7.5 Trial timelines and milestones: Table removed and replaced with the approved statement.
		12	31-May-19	19	02-Jul-19	Increase in the number of sites performing quality assurance assessments
		11	13-Mar-19	18	03-Apr-19	Inclusion of additional quality assurance assessment
		10	30-Nov-18	16	19-Dec-18	Update in recruitment duration (Nov 2019) sec.7.5
		9	16-Feb-18	10	21-Mar-18	All references to Trial Coordinator changed to Trial Manager. Minor change to text page 19 paragraph 4 regarding use of text messaging templates for follow up data collection and deleting of messages from trial mobile at the end of the trial. Also includes amended Trial timeline and milestones table with revised recruitment target and increased number of sites to 20
		8	15-Jan-18	9	26-Feb-18	Change to CI maternity cover. Addition of dates (May 2017 to January 2018). Addition of new sites
		7	01-Aug-17	8	18-Sep-17	Statement added to exclusion criteria to confirm "low dosage Aspirin use" is not a contraindication to receiving PRP
		6	21-Apr-17	7	25-May-17	CI maternity cover addition of Martin Underwood
		5	15-Feb-17	6 - HRA amendment non-substantial.	N/A - HRA amendment non-substantial	Minor changes to the protocol. Clarification of cancer to "active cancer"
		4	30-Sep-16	4	30-Nov-16	change to the timeline to reflect the addition of extra sites.
		3	03-Mar-16	2	08-Apr-16	clarifications to the protocol as requested by the TSC, see tracked version of the document.
		2	21-Dec-15	1	15-Feb-16	minor changes to follow up, change to eligibility criteria, see tracked version of the document.
1	24-Aug-15	Initial approval	30-Oct-15	N/A		
3.1	ATM Patient information sheet - Full	7	03-Dec-19	20	07-Jan-20	Updated with extension information and include clarification around next of kin contact information. Section 6, page 3 – Rewording paragraph to be clearer around the use of text messages. Section 6, page 4 and Section 13, page 5 – additional lines added in relation to next of kin contact information. Section 14, page 5 – New recruitment and study timeline dates stated.
		6.1	04-Jan-19	17	14-Jan-19	Update in recruitment duration Nov 2019
		6	23-Mar-16	2	08-Apr-16	minor changes for clarification which were further requested by TSC post meeting in February 2016 - see TSC correspondence in section 9.3 of the TMF, and the tracked documents.
		5	01-Mar-16	N/A	N/A	this was a working version that was not sent for REC approval. Minor changes to reflect a change to the follow up schedule as requested by the TSC (see TSC correspondence in section 9.3 of the TMF). 2 week appointment will be done via telephone and 6 month follow up via post.
		4	10-Feb-16	1	15-Feb-16	minor re-wording, see tracked document
		3	21-Dec-15	1	N/A	Sent to REC as part of amendment 1, however, REC requested changes (see REC correspondence in section 4.2 of the TMF) which are tracked, see document for minor changes.
		2	07-Oct-15	Initial approval	30-Oct-15	REC requested further information regarding blood being taken
		1	24-Aug-15	N/A	N/A	Submitted to REC but not approved.
3.1	ATM Patient information sheet - Summary	4	01-Mar-16	2	08-Apr-16	minor changes for clarification as requested by TSC, see tracked documents.
		3	21-Dec-15	1	15-Feb-16	minor changes to reflect a change to the follow up schedule. 2 week appointment will be done via telephone and 6 month follow up via post.
		2	07-Oct-16	N/A	N/A	working version, not submitted to REC
		1	24-Aug-15	Initial Approval	30-Oct-15	
3.1	Analysis of PRP PIS	2	31-May-19	19	02-Jul-19	Wording update to cover other hospitals
		1	13-Mar-19	18	03-Apr-19	N/A
3.2	ATM Consent Form	5	26-Nov-19	20	07-Jan-20	Updated with extension information and include clarification around next of kin contact information. Bullet 1 – Updated document version number and date. Bullet 9 – Clarification regarding text message consent and their use within the study.
		4	23-Mar-16	2	08-APR-2016	minor change to order of statements and change to the version number for PIS
		3	21-Dec-15	1	15-FEB-2016	minor change to order of statements and change to the version number for PIS
		2	07-Oct-16	Initial Approval	30-OCT-2015	REC requested changes to the document
		1	24-Aug-15	N/A	N/A	Submitted to REC but not approved.
3.2	Analysis of PRP Consent form	2	31-May-2019	19	02-JUL-2019	Wording update to PIS version
		1	13-Mar-19	18	03-Apr-2019	N/A
3.5	PRP analysis Advert	2	31-May-19	19	02-JUL-2019	Wording update to cover other hospitals

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3.5	ATM Recruitment Poster	1	13-Mar-2019	18	03-Apr-2019	N/A
3.5	ATM Recruitment Poster	1	21-Dec-15	2	08-Apr-16	new document requested by sites to support the recruitment of patients to the trial by informing/ reminding staff at site about the trial.
3.6	ATM GP letter	2	21-Dec-15	1	15-Feb-16	Wording: use of word patient, changed to participant.
3.6	ATM GP letter	1	24-Aug-15	Initial Approval	30-Oct-15	N/A
3.7	ATM PIS Postal Cover letter	1	11-Jan-16	2	08-Apr-16	new document required to enable sites to post out PIS to patients
3.7	ATM Notification of Randomisation letter	1	24-Aug-15	Initial Approval	30-Oct-15	N/A
3.7	ATM Participant Post injection care and information	2	21-Dec-2015	1	15-Feb-16	additional information about tendinopathy as required by funder
3.7	ATM Participant Post injection care and information	1	24-Aug-15	Initial Approval	30-Oct-15	N/A
3.7	ATM Script for Text Messages	1	09-Jun-2016	Initial Approval	30-Nov-16	Text message wording to send to participants that have consented to contact by text messages.
3.7	ATM 3 Month Questionnaire Cover Letter	2.1	03-Dec-19	20	07-Jan-20	To ensure that participants are aware of where to find our data transparency statement we propose to addition of line to all letters send to participants directing them to the Trial website and signature update.
3.7	ATM 3 Month Questionnaire Cover Letter	2	29-Nov-18	16	19-Dec-18	Change of trail office address and phone contact details.
3.7	ATM 3 Month Questionnaire Cover Letter	1	24-Aug-15	Initial Approval	30-Oct-15	N/A
3.7	ATM 6 Month Questionnaire Cover Letter	4.1	03-Dec-19	20	07-Jan-20	To ensure that participants are aware of where to find our data transparency statement we propose to addition of line to all letters send to participants directing them to the Trial website and signature update.
3.7	ATM 6 Month Questionnaire Cover Letter	4	28-Nov-18	16	19-Dec-18	Change of trail office address and phone contact details.
3.7	ATM 6 Month Questionnaire Cover Letter	3	21-Mar-2016	2	08-Apr-16	Re-wording of the previously added text relating to a £5 voucher, as requested by TSC.
3.7	ATM 6 Month Questionnaire Cover Letter	2	21-Dec-15	1	15-Feb-16	Following text added: "Thank you for returning your three month questionnaires for the Achilles Tendinopathy management (ATM) trial. We would like to take the opportunity to say thank you for your participation in the trial. As a token of our appreciation for your support and participation, we have enclosed a £5 voucher. "
3.7	ATM 6 Month Questionnaire Cover Letter	1	24-Aug-15	Initial Approval	30-Oct-15	N/A
3.7	ATM 6 Month Questionnaire Cover Letter (reminder)	2.1	03-Dec-19	20	07-Jan-20	To ensure that participants are aware of where to find our data transparency statement we propose to addition of line to all letters send to participants directing them to the Trial website and signature update.
3.7	ATM 6 Month Questionnaire Cover Letter (reminder)	2	29-Nov-18	16	19-Dec-18	Change of trail office address and phone contact details.
3.7	ATM 6 Month Questionnaire Cover Letter (reminder)	1	21-Feb-17	7	25-May-17	Removal of reference to £5 gift voucher
3.7	ATM 3 Month Thank You	3.1	03-Dec-19	20	07-Jan-20	To ensure that participants are aware of where to find our data transparency statement we propose to addition of line to all letters send to participants directing them to the Trial website and signature update.
3.7	ATM 3 Month Thank You	3	29-Nov-18	16	19-Dec-18	Change of trail office address and phone contact details.
3.7	ATM 3 Month Thank You	2	21-Dec-15	1	15-Feb-16	minor re-wording, see tracked document
3.7	ATM 3 Month Thank You	1	24-Aug-15	Initial Approval	30-Oct-15	N/A
3.7	ATM 6 Month Thank You (£5 voucher)	2.1	03-Dec-19	20	07-Jan-20	To ensure that participants are aware of where to find our data transparency statement we propose to addition of line to all letters send to participants directing them to the Trial website and signature update.
3.7	ATM 6 Month Thank You (£5 voucher)	2	29-Nov-18	16	19-Dec-18	Change of trail office address and phone contact details.
3.7	ATM 6 Month Thank You (£5 voucher)	1	16-Aug-18	14	25-Sep-18	New cover letter required to send with back log of £5 vouchers
3.7	ATM 6 Month Thank You	3.1	03-Dec-19	20	07-Jan-20	To ensure that participants are aware of where to find our data transparency statement we propose to addition of line to all letters send to participants directing them to the Trial website and signature update.
3.7	ATM 6 Month Thank You	3	29-Nov-18	16	19-Dec-18	Change of trail office address and phone contact details.
3.7	ATM 6 Month Thank You	2	21-Dec-15	1	15-Feb-16	minor re-wording, see tracked document
3.7	ATM 6 Month Thank You	1	24-Aug-15			
3.7	ATM 6 month unblinding letter (placebo or PRP)	3	29-Nov-18	16	19-Dec-18	Change of trail office address and phone contact details.
3.7	ATM 6 month unblinding letter (placebo or PRP)	2	16-Aug-18	14	25-Sep-18	Minor change to wording to remove "your trial allocation" and replace with "it was a..."
3.7	ATM 6 month unblinding letter (placebo or PRP)	1	13-Jul-17	8	18-Sep-17	New letter required for patients requested treatment allocation. To be used instead of ATM 6 Month Thank you letter
3.7	ATM End of trial letter	2	28-Nov-18	16	19-Dec-18	Change of trail office address and phone contact details.
3.7	ATM End of trial letter	1	24-Aug-15	Initial Approval	30-Oct-15	N/A
3.7	ATM Transparency Statement (GDPR)	2	03-Dec-19	20	07-Jan-20	the GDPR is undertaking a task (research) in the public interest." and "The University of Warwick will process your next of kin's personal data; their name, address and phone number for the purpose(s) of making contact with them in relation to your participation in this clinical trial if we are unable to contact you. The legal basis for processing this personal data is legitimate interest. Your next of kin's personal data will not be shared or disclosed to any third parties external to the University of Warwick. Please inform your next of kin of the above information if they are not already aware."
3.7	ATM Transparency Statement (GDPR)	1	19-Aug-19	N/A	N/A	N/A
6.6	ATM Site delegation log	1	22-Feb-16	N/A	N/A	N/A
10.2	ATM Trial intervention procedures	7	18-Oct-16	N/A	N/A	Addition of useful information, text added to instructions on page 3: "It may help to squeeze the barrel at the level of the plunger to do this."
10.2	ATM Trial intervention procedures	6	20-Sep-16	N/A	N/A	GLO Finn protocol for preparing PRP changed. Only 1ml anticoagulant to be mixed with 9ml blood, rather than previously 1.5ml anticoagulant to be mixed with 8.5ml blood.
10.2	ATM Trial intervention procedures	5	06-Jun-16	N/A	N/A	minor rewording in relation to removing the plunger

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		4	23-May-16	N/A	N/A	extra clarification on the 1st centrifugation
		3	26-Apr-16	N/A	N/A	minor changes to order
		2	24-Mar-16	N/A	N/A	additional information added
		1	22-Feb-16	N/A	N/A	N/A
10.3	GP/health professional email	1	13-Mar-19	18	03-Apr-2019	N/A
		3	26-Apr-19			Removal of DOB
11.1	ATM Screening and Recruitment log - Main log	2	05-May-16	N/A	N/A	for office use only sections added and log for date field added to the screening log.
		1	02-Apr-16	N/A	N/A	N/A
11.1	ATM Patient Tracker Form	1	05-May-16	N/A	N/A	N/A
		3	03-Mar-17	N/A	N/A	exclusion criteria: "cancer" clarified as "active cancer"
11.4	ATM Eligibility form	2	12-JUL-2016	N/A	N/A	age changed from 16 to 18 to reflect protocol change on 03-MAR-2016, approved by REC on 08-APR-2016.
		1	14-Dec-15	N/A	N/A	N/A
		4	25-Apr-19	N/A	N/A	Removal of NHS/CHI number field
11.4	ATM Randomisation CRF	3	05-May-16	N/A	N/A	change of gender order, merge of first name and surname columns, change to wording of stratification variables
		2	26-Apr-16	N/A	N/A	question order change to allow for easier navigation. Email added, fax removed.
		1	21-Dec-15	N/A	N/A	N/A
11.4	ATM Baseline CRF	4	16-Mar-17	N/A	N/A	addition of relationship to contact 1 and 2 of patient contact details form (page 6)
		3	08-Mar-17	N/A	N/A	change to page 4 tick boxes realigned ethnicity section
		2	01-Mar-16	N/A	N/A	see tracked document
		1	21-Dec-15	N/A	N/A	N/A
		4 - single	07-Apr-17	7	25-May-17	1st question amended, Rewording of complications data categories & addition of Visual pain score
		3 - single	30-SEPT-2016	4	30-Nov-16	Addition of a pain score to this CRF
11.4	ATM 2 week Follow up CRF - single	4 - bilateral	07-Apr-17	7	25-May-17	1st question amended, Rewording of complications data categories & addition of Visual pain score
		3 - bilateral	30-Sep-16	4	30-Nov-16	Addition of a pain score to this CRF
		2 - bilateral	01-Mar-16	3	04-Oct-16	new form specifically for patients that have been treated bilaterally, as we want to capture any complications experienced by the trial tendon and the non-trial tendon. This form allows the capture of both sets of information.
		2	01-Mar-16	2	08-Apr-16	minor changes to reflect that the 2 week appointment will be done via telephone
		1	21-Dec-15	1	15-Feb-16	N/A
11.4	ATM Intervention Delivery Form	2	18-Jul-17	N/A	N/A	to confirm intervention delivery to trial tendon. For bilaterla patients to confirm if intervented delivered to non trial tendon
		1	14-Dec-15	N/A	N/A	N/A
11.4	ATM SAE Form (Initial and Follow up)	2	26-Jul-2016	N/A	N/A	N/A
		1	14-Dec-15	N/A	N/A	N/A
11.4	ATM SAE continuation form	1	14-Dec-15	N/A	N/A	N/A
11.4	ATM Withdrawal Form	2	22-Feb-16	N/A	N/A	see tracked document
		1	14-Dec-15	N/A	N/A	N/A
11.4	ATM Protocol Deviation or Note to file	1	14-Dec-15	N/A	N/A	N/A
11.4	ATM Notification of Death Form	1	14-Dec-15	N/A	N/A	N/A
11.4	ATM Change of contact details form	1	14-Dec-15	N/A	N/A	N/A
11.5	ATM Baseline Participant Questionnaire	2	01-Mar-16	2	08-Apr-16	minor re-numbering due to error, see tracked document
		1	21-Dec-15	1	15-Feb-16	N/A
		4	28-Nov-18	16	19-Dec-18	Change of trail office address and phone contact details.
		3	07-Apr-17	7	25-May-17	1st question amended, Rewording of complications data categories. Amendment to Contact Details form
11.5	ATM 3 month Participant Questionnaires - bilateral	2	01-Mar-16	3	04-Oct-16	New document to capture bilateral data. Duplication of the complications section to allow for capture of trial tendon and non-trial tendon complications.
		4	28-Nov-18	16	19-Dec-18	Change of trail office address and phone contact details.
		3	07-Apr-17	7	25-May-17	1st question amended, Rewording of complications data categories. Amendment to Contact Details form
		2	01-Mar-16	2	08-Apr-16	minor re-numbering due to error, see tracked document
		1	21-Dec-15	1	15-Feb-16	N/A
		5	28-Nov-18	16	19-Dec-18	Change of trail office address and phone contact details.
		4	07-Arp-17	7	25-May-17	1st question amended, Rewording of complications data categories. Amendment to Contact Details form
11.5	ATM 6 month Participant Questionnaires - bilateral	3	21-Mar-16	3	04-Oct-16	New document to capture bilateral data. Duplication of the complications section to allow for capture of trial tendon and non-trial tendon complications.
		5	28-Nov-18	16	19-Dec-18	Change of trail office address and phone contact details.
		4	07-Apr-17	7	25-May-17	1st question amended, Rewording of complications data categories. Amendment to Contact Details form
		3	21-Mar-16	2	08-Apr-16	minor re-numbering due to error, see tracked document

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	Questionnaires - Single	2	01-Mar-16	N/A	N/A	this was a working version that was not sent for REC approval. See tracked document for minor changes.
		1	21-Dec-15	1	15-Feb-16	