

- 1 1. **Full Title: What are the barriers to upper limb splint adherence, and how is**
- 2 **adherence measured? A systematic review**
- 3 2. **Short Title: Adherence to splints: A systematic Review**
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- 10 6. **Keywords:** Splint; adherence; systematic review; hand therapy.
- 11 7. **Declaration of conflicting interests:** EB is Chief Investigator, AD Co-Chief
- 12 Investigator and AS and NJ are co-applicants of Flexor Injury Rehabilitation Splint
- 13 Trial (FIRST) - an NIHR HTA funded Multi-centre RCT NIHR133582. No data
- 14 directly collected from FIRST is included in this review. IS and JAM have no
- 15 declarations of interest to declare.
- 16 8. **Funding statement:** This work was partly funded by an NIHR/HEE Pre-Doctoral
- 17 Fellowship completed by EB at the University of Nottingham and supervised by
- 18 AD.
- 19 9. **Ethical approval declaration:** Not applicable
- 20 10. **Informed consent declaration:** Not applicable
- 21 11. **Contributorship details:** EB conceived and led the project; EB, AD and NAJ
- 22 designed the project; EB, JAM, IS and AS reviewed the abstracts, manuscripts
- 23 and performed data extraction; EB performed the analysis, EB and JAM wrote
- 24 the paper; all authors reviewed the manuscript; AD and NJ supervised the
- 25 project.

26

27

28 1. INTRODUCTION

29 Non-adherence to treatment is a significant concern in healthcare. As well as being
30 associated with an increasing health burden and a negative impact on health
31 outcomes overall, non-adherence is also associated with higher healthcare costs¹. In
32 clinical practice, the World Health Organisation (WHO) defines adherence as ‘the
33 extent to which a person’s behaviour – taking medication, following a diet, and/or
34 executing lifestyle changes, corresponds with agreed recommendations from a
35 health care provider ¹. Adherence is like compliance, this being previously defined as
36 ‘the extent to which the patient’s actual history of drug administration corresponds to
37 the prescribed regimen’, although the use of the word adherence has superseded
38 the term compliance due to the negative connotations of the latter ^{2,3}.

39 The multi-dimensional adherence model was developed by WHO in 2003¹. This
40 report identified five domains associated with non-adherence more broadly: Social
41 and economic (age, gender, ethnicity, employment status, family/social dysfunction,
42 drug/alcohol issues and education level), Health-care team and system (patient-
43 provider relationship, follow up length), condition related (type of injury, prognosis,
44 co-morbidities), therapy related (complexity, duration of treatment, interference with
45 lifestyle/ activities of daily living/work, immediacy of benefit, discomfort) and patient
46 related (physical factors, cognitive impairment and psychological factors). This report
47 aimed to raise awareness of the problem, highlight the clinical and cost impact of
48 non-adherence, and give clinicians specific guidance on how to manage non-
49 adherence, but was primarily focussed on medication adherence⁴.

50 Within upper limb therapy, adherence to splint wearing is of particular importance.
51 Splinting forms a key part of the rehabilitation of most upper limb pathologies,

52 including osteoarthritis of the hand⁵, tendon injuries of the hand ⁶, bony and non-
53 bony wrist pathology ⁷, peripheral neuropathies ^{8,9}, and post-stroke spasticity of the
54 upper limb ¹⁰, although the evidence base underpinning these interventions is
55 variable ¹¹. Earlier publications have indicated that adherence to splinting is
56 inconsistent, with some studies identifying non-adherence rates of up to 70%,
57 although there are substantial differences in how this is measured in different studies
58 ¹², and what factors influence adherence¹³. There is a wealth of data on patient
59 adherence to pharmacological treatments ^{1,14,15}, but much less on adherence to
60 therapy interventions as identified by a systematic review conducted in 2020¹³.
61 Interestingly, some studies have reported that having a poor functional baseline as
62 well as transport burden to appointments has been identified as factors associated
63 with poor adherence to rehabilitation regimes¹⁶. These are likely exacerbated by
64 restrictions placed on mobility and driving due to the nature of the patient's condition
65 in these circumstances¹⁶.

66 Given the near ubiquity of splinting in the management of upper limb pathology, an
67 appreciation of adherence to treatment is vital, both to maximise patient
68 responsiveness to therapy regimes and to identify potential experimental targets that
69 could improve the use of splinting in the future. This systematic review aims to
70 identify barriers to adherence to upper limb splints, and to compare and synthesise
71 the evidence related to measuring and quantifying splint adherence.

72 **2. METHODS**

73 This review was developed and completed using the PRISMA guidelines for
74 reporting systematic reviews¹⁷ and registered with PROSPERO

75 (CRD42023403415)¹⁸. The full details of the protocol can be viewed at:
76 https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42023403415.

77 The terms splint, orthosis and brace are frequently used interchangeably in the
78 literature depending on the location and the clinical background of the study team.
79 The American Society of Hand Therapists (ASHT) specifically define an orthosis as "
80 A rigid or semi-rigid device that supports a weak or deformed body member or
81 restricts or eliminates motion in a diseased or injured part of the body. An orthosis
82 can be custom fabricated, custom fit or prefabricated "¹⁹. In this review we will use
83 the term 'splint' to reflect the commonly preferred terminology of United Kingdom
84 (UK) based hand therapists, to include 'splint', 'orthosis' or 'brace' that provided an
85 element of immobilisation or controlled mobilisation to the affected part of the upper
86 limb, which could be removed by the patient under the direction of their clinical team.

87 *2.1. Search Strategy*

88 A systematic literature search was carried out to identify articles reporting on the
89 methods used to measure adherence and the barriers to wearing splints in the upper
90 limb following traumatic injuries. The search strategy was developed by the research
91 team and took place between February and May 2023, and was updated in
92 December 2023.

93 A systematic search of databases: MEDLINE, CINAHL (via EBSCOhost), PubMed,
94 EMBASE, and ScienceDirect was conducted using key search terms and their
95 related terms. Table 1. provides detail on the search terms used.

96 A decision to search databases from 2009 up to the current year was made because
97 of the publication of a previous systematic review on splint adherence ²⁰, and a
98 paper reviewing the methods used to measure adherence ²¹. The aim of this current

99 review therefore was to update and combine these two previously published reviews
100 in the field of upper limb splinting, given that additional articles had been published
101 related to splint adherence and the measurement of adherence since these
102 publications.

103 *2.2. Eligibility criteria*

104 The inclusion criteria included patients 18 years and over, traumatic injuries of the
105 upper limb and studies reporting on: splint adherence as a primary or secondary
106 outcome OR reporting on barriers to splint adherence OR reporting on methods used
107 to assess splint adherence.

108 The exclusion criteria were articles published prior to 2009, systematic or other
109 literature reviews, articles relating to chronic long-term conditions e.g., rheumatoid
110 arthritis, case series, cadaveric or other non-human studies and non-English articles.
111 Full eligibility criteria can be seen in Table 2.

112 *2.3. Screening and article selection*

113 The initial search of the databases was carried out by the primary author (EB) and all
114 articles were exported to Rayyan.ai (www.rayyan.ai), reference management
115 software. Table 2. provides full details of the search strategy used. Once all articles
116 had been exported, duplicate articles were removed. The remaining titles and
117 abstracts were then screened for eligibility according to the inclusion and exclusion
118 criteria by three reviewers (EB, JM, IS). The full texts of eligible studies were
119 retrieved, and subject to screening independently by three reviewers (EB, JM, IS)
120 against the full inclusion and exclusion criteria. Any uncertainties were initially
121 discussed within the screening team, and a fourth assessor was used to resolve any
122 discrepancies (AS). Finally, the reference lists of the full text articles included in this

123 review were hand searched for any additional articles of interest. These papers were
124 then subject to screening (EB, JM, IS), and any eligible articles added for final review
125 if they satisfied the inclusion and exclusion criteria.

126 *2.4. Data Extraction*

127 A standardised data extraction pro-forma was developed by the study team (EB, JM,
128 IS) and data was extracted and inputted systematically by the individual reviewing
129 each paper using this pro-forma (EB, JM, IS, AS). Data capture included:
130 demographic data, study design, country of study, study duration, sample size, study
131 population (diagnosis, age, and sex), type of splint, duration of wear, and barriers to
132 splint wearing (including patient reported barriers and patterns observed by the study
133 teams). The method of recording adherence was also captured.

134 Due to the heterogeneity of the studies, quantitative analysis was not possible,
135 therefore synthesis of extracted data was narrative.

136 *2.5. Quality Assessment*

137 The quality of the studies being reviewed was assessed using Version 2 of the
138 Cochrane risk-of-bias tool for randomised trials (RoB 2)²² for the three RCTs^{23–25},
139 and the critical appraisal skills programme (CASP) checklist appropriate for the type
140 of study being reviewed e.g. qualitative study, cohort study etc²⁶ for the remaining
141 studies. All studies were evaluated by individual reviewers (EB, JM, IS) and an
142 appropriate form was completed for each assessment.

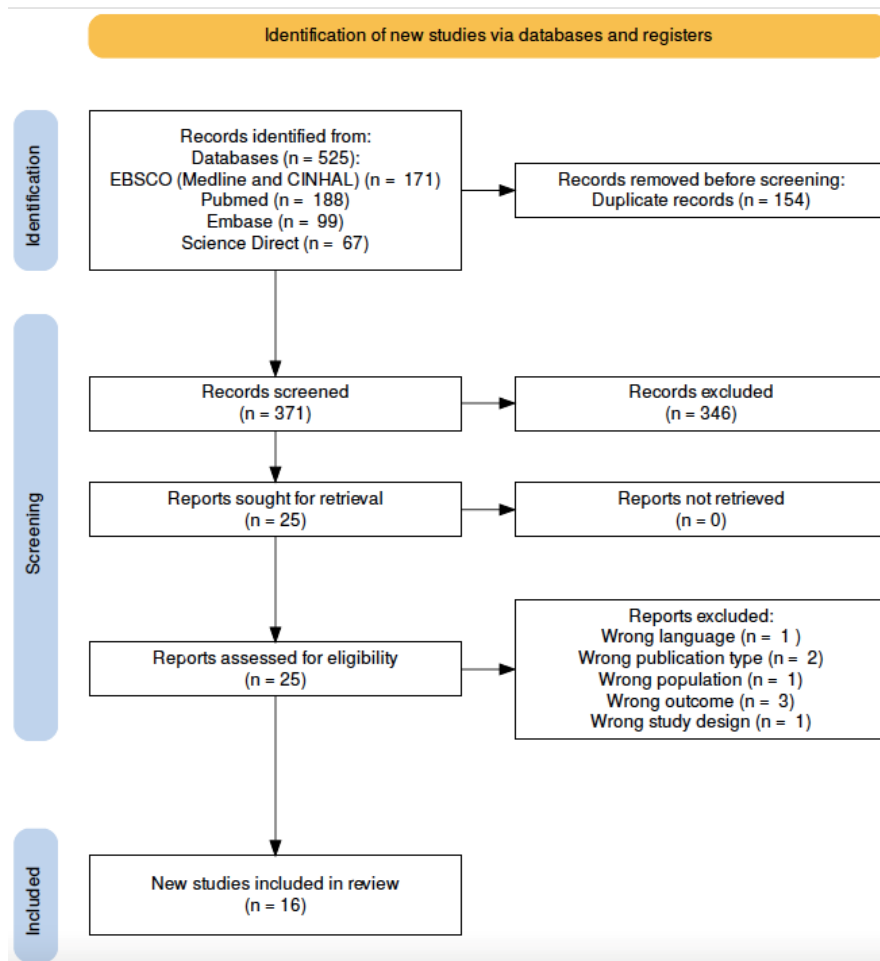
143

144 **3. Results**

145 A total of 525 records were identified from the original search with 371 records
146 remaining after removal of duplicates. Of these, 25 full texts were then screened for

147 eligibility, of which 16 satisfied the inclusion and exclusion criteria and were subject
 148 to full review. A total of 16 articles were included in the final review. These included
 149 articles that measured adherence (n=14), quantified adherence (n=10) or barriers to
 150 adherence (n=13), or a combination of these.

151



152

153 Figure 1. PRISMA 2020 review flow diagram

154 *3.1. Study Design*

155 Individual study details are available in Table 3. The 16 studies included 3
 156 randomised controlled trials (RCTs) ²³⁻²⁵, 3 qualitative studies²⁷⁻²⁹, 8 cohort series ³⁰⁻
 157 ³⁷, 1 prospective observational study³⁸, and 1 mixed methods study ³⁹.

158

159 Study duration data were available for thirteen studies and ranged from 3 months to
160 47 months with an average of 23 months. The mean sample size was 56
161 participants, ranging from 12 to 133.

162

163 *3.2. Demographic details*

164 The mean age of participants was 44.5 years (available in 10 studies) with most
165 participants being men (mean across all studies 58% male). All study participants
166 had a history of a traumatic injury of their upper limb, which required immobilisation
167 or partial immobilisation using a removable splint. Five studies involved splinting of
168 the shoulder or axilla region^{25,31,34,36,38} and eleven to the wrist or hand<sup>23,24,27–
169 30,32,33,35,37,39</sup>

170

171 *3.3. Methods of Measuring Adherence*

172 Out of the sixteen studies included in this review, fourteen studies measured
173 adherence. The remaining studies did not include a direct measure of adherence but
174 were included in the review as they reported on potential barriers to adherence.
175 There was significant variation in the methods used to measure adherence (Table
176 4.). Eight studies^{23,27,30,33,35,37,39,40} relied on patient or therapist reported data either
177 in the form of novel questionnaires, interview, or other non-structured means to
178 measure adherence. Four studies utilised an already established classification
179 system tool, either the medical adherence measurement score (MAM score)^{31,34}, or a
180 modified version of a classification system^{24,32} developed by Groth et al⁴¹. Two
181 studies utilised temperature sensors fitted within the splint to monitor adherence^{36,38}.

182

183 *3.4. Methods used to quantify Adherence.*

184 Ten studies reported the method they used to quantify adherence (Table 4.). The
185 studies using the MAM reported the MAM score expressed as a percentage^{31,34}.
186 The two studies utilising the modified Groth classification^{24,32} reported adherence
187 using a modified version of the 3-point scale as described by Groth⁴¹. Grubhofer et al
188 and Weir et al³⁸ presented the adherence data captured by temperature sensors as
189 a percentage and then used this to classify participants as having either high
190 compliance (equal to or more than 80% wear time prescribed), or low compliance
191 (less than 80%). The remaining four studies developed their own classification
192 systems. Azad et al³⁷ classified anyone who removed their splint as non-adherent.
193 Kolmus et al²⁵ classified participants as adherent if they wore their splint for four or
194 more days in a week for six hours or more, and four or more nights a week for four or
195 more hours. Mortazavi et al³⁵ took a similar approach and classified those who wore
196 their splint more than 5 nights a week as adherent. In contrast to this, Savas et al³³
197 classified full adherence as participants who wore their splint 100% of the prescribed
198 time and never used their hand, partial adherence for those who did not wear their
199 splint 100% of the time, but never used the injured hand and non-adherence as
200 participants who did not wear their splint 100% of the time and used the injured
201 hand.

202

203 *3.5. Barriers to Splint Adherence*

204 Barriers to adherence were presented in thirteen out of the sixteen studies included
205 in this review. Interestingly, most of the barriers were reported by the clinical
206 investigator teams themselves, rather than being directly reported by participants.
207 These investigator-reported barriers were either assumed based on the teams'
208 clinical opinion^{23,24,32,35,39} or inferred based on correlations made from the study data

209 being analysed^{31-34,36}. Five studies presented barriers that had been reported by
210 patients themselves^{25,27,28,33}. A summary of these barriers is presented in Table 5.

211

212 Therapist reported barriers included the financial burden of attending
213 appointments^{23,39}, a decreased perception of injury and rehabilitation complexity^{28,39},
214 language barriers and decreased comprehension of instructions³⁹ and splint
215 discomfort and stiffness³⁶. Roh et al³² also suggested that there was a correlation
216 between adherence and decreased occupational level, physical activity, and
217 psychological factors. A link between adherence and clinical empathy was also
218 made²³.

219

220 Several studies used demographic data and adherence data to make inferences
221 regarding adherence. Roh et al³² reported a strong correlation between health
222 literacy and adherence and suggested that poor health literacy was linked to poor
223 adherence. Two further studies discussed the link between psychological well-being
224 and adherence but reported conflicting findings with one study suggesting a link
225 between Beck's depression score and adherence³³ and another study reporting no
226 link between adherence and the psychological related data³¹. Correlations were also
227 noted between being a smoker and non-adherence³⁴. Male sex was also linked to
228 increased non-adherence³¹.

229

230 Patient reported barriers to adherence were cited as being predominantly due to
231 limitations in functional activities and the hygiene and appearance of the
232 splint^{25,28,29,33}. Participants reported significant difficulty in carrying out daily
233 functional activities such as caring for themselves^{29,33}, caring for their baby or

234 children^{25,33}, cooking^{25,33}, driving³³ and carrying out their job^{25,28,29,33}. Savaş an
235 Aydoğan³³ listed many factors that contributed to participants removing their splint
236 (23 in total). In addition to those noted above, necessary religious activities were also
237 linked to adherence. This led these authors to conclude that to perform daily tasks,
238 participants had to be non-adherent²⁵.

239

240 Kolmus et al²⁵ also reported that participants removed their splint early if they felt
241 their clinical outcome (range of movement) had improved. The belief that outcome
242 could be affected by adherence was also reported by O'Brien et al²⁸. They
243 suggested that if participants in their study could positively influence their outcome,
244 they were more likely to be adherent to their splint.

245

246 **3.6. Methodological quality**

247 Of the three RCTs included in this trial²³⁻²⁵, two were assessed as 'low risk of bias
248 ^{24,25} and one study was considered as having as 'some concerns' ²³. However,
249 although The CASP checklist²⁶ applied to all the studies in this review is not
250 designed to provide a reporting outcome, a summary can be found in the
251 supplementary material Table 1 as a measure of quality.

252

253 **4. Discussion**

254 Despite being a critical aspect of healthcare provision, adherence to treatment is
255 often poorly reported and under investigated in clinical research. Upper limb splinting
256 therapy is no exception to this. In this present systematic review, we have identified
257 a wide variety in the methods used in the measurement of adherence, with no

258 obvious clear standard practice. We also have identified several different factors that
259 have been associated with poor adherence to splinting in a clinical context.

260

261 *4.1. Measuring Adherence*

262 The ability to measure splint adherence accurately and objectively, and assess a
263 participant as being adherent to wearing their splint, is not only important in clinical
264 practice, but also in research settings. In healthcare, poor adherence often leads to
265 poor outcomes and an increase in usage, which is costly both for patients and for the
266 National Health Service (NHS)^{20,42,43}. Being able to measure adherence has
267 therefore been identified as a major global challenge⁴³. In research, for those trials
268 aiming to compare one treatment modality to another, it is essential to understand
269 the participants' adherence to the treatment. Researchers need to be able to
270 confidently classify someone as being adherent to a splint or not to mitigate the risk
271 of a type 2 error in their trial. If participants are not adherent, the study cannot show
272 the effectiveness of interventions with any certainty.

273

274 In this present review, a variety of methods of assessing adherence were employed,
275 and it is notable that there was not one predominant technique employed. Patient or
276 clinician reported measures of adherence (interview, diaries self-reported patterns)
277 are commonly used both in clinical practice⁴⁴ and in clinical trials, particularly in
278 relation to pharmacological studies⁴⁵. They are a quick, cheap, and easy method of
279 establishing adherence rates. However, it is well documented that patients reported
280 overestimate their adherence significantly⁴⁶. To improve the reliability of adherence
281 data several studies reported in this review developed their own novel
282 questionnaires^{25,33}, however the specific details of these questionnaires were

283 lacking ²⁵ and therefore the methodological robustness of these questionnaires
284 remains unclear.

285

286 This review also highlighted the use of two established adherence measurement
287 tools namely the MAM ⁴⁷ and the Groth classification system⁴¹. The MAM is a
288 screening tool that aims to identify self-reported barriers to adherence and assess
289 adherence⁴⁷. This tool was originally developed for the paediatric population. The
290 Groth classification system measures adherence by combining information on the
291 patients' splint wear, exercise programme and attendance to their therapy
292 appointments⁴¹. Although these measures attempt to provide a more reliable,
293 quantifiable measure of adherence, they are non-validated measures, relying
294 predominantly on patient or therapist reported data, and therefore are subject to the
295 same limitations as other self-reported measures of adherence.

296

297 Due to these limitations in patient reported adherence data, there remains a lack of a
298 gold standard method of measuring adherence ¹⁵. In recent years there has been a
299 move towards using electronic sensors to monitor adherence, particularly for
300 measuring adherence to medication. These sensors can be embedded in medical
301 devices to measure temperature, pressure, or movement changes and this provides
302 quantitative data, which can be used to classify adherence. The 'Orthotimer' sensor
303 and 'HOB0 MX2201' are two such devices. These temperature sensors are embedded
304 within a prescribed orthosis and monitors temperature at pre-defined time intervals to
305 measure on/off wear. The data are then downloaded and analysed to give an
306 objective measure of adherence. In this the review, the studies by Grubhofer et al³⁸
307 and Weir et al ³⁶ embedded these sensors in shoulder abduction brace/sling, and

308 adherence measured by comparing the wear time data captured from the sensors,
309 with the prescribed wear time.

310

311 The use of electronic sensors may appear to provide the accurate, reliable data
312 required to measure adherence. However, a recent systematic review of electronic
313 devices or sensors demonstrates that many of the sensors used are not practical for
314 studies outside the laboratory and there are still accuracy concerns, with many of
315 them either under or over estimating adherence ⁴⁴. For example, temperature
316 sensors are reported to be sensitive to ambient temperature and therefore may give
317 a false reading of don/doff time⁴⁴.

318

319 The other challenge facing clinicians and researchers is the quantification of
320 adherence. They must use the adherence data to then define someone as being
321 adherent or non-adherent to the prescribed intervention. This review has
322 demonstrated that there is also no consensus on the methods used to quantify
323 adherence. Some authors suggest that adherence should be 100% to be classified
324 as adherent^{33,37}. However, in relation to splint wearing this is likely to be
325 unachievable. We would suggest that a more pragmatic approach to providing a
326 meaningful adherence classification may be to calculate the measure of crude
327 adherence and reduce this by an acceptable proportion of non-adherence, to give a
328 threshold that must be met to be classified as being adherent. In relation to splint
329 wearing, this may be, for example activities such as wound care, hand washing,
330 hand therapy treatment sessions or removing the splint for religious practices. This
331 approach would allow investigators to set a percentage threshold, that could be used
332 to classify adherence. If the adherence data shows a percentage wear time above

333 the threshold they could be classified as adherent and below that threshold. This
334 was also the broad approach Grubhofer et al ³⁸ and Weir et al ³⁶ took using a
335 threshold of 80%. Anything above this was classed as adherent, anything below this
336 non-adherent.

337

338 It should be noted that the distribution of the wear time could also be an important
339 consideration in adherence clinically. For example, someone may be prescribed to
340 always wear a splint for five weeks, and using this classification they could remove
341 their splint for a whole week and still be deemed highly compliant. Investigators may
342 therefore also wish to set additional rules such as the splint must be worn each day
343 and removed for no longer than 30 mins at a time. Although this may provide a more
344 accurate measure of adherence, it also adds to the complexity of data analysis.

345

346 When attempting to measure adherence we must also consider the functional
347 activities that are carried out whilst the splint has been removed. In clinical practice,
348 the types of activities that a participant carries out with their hand whilst not wearing
349 the splint may be just as important on outcome as the total wear time and
350 adherence. For example, if someone has had a finger flexor tendon repair and wears
351 their splint 95% of the time but removes it to change a car tyre - they may still be
352 classified as highly adherent, but that one activity may lead to tendon re-rupture and
353 failure of treatment. Some of the papers included in this review included questions
354 around the functional use of the hand whilst not wearing the splint ³³ or asked about
355 the reasons why participants removed their splint and barriers to adherence ²⁵, a
356 question that is also included in the MAM used by Silverio and Cheung³⁴ and
357 Mercurio et al ³¹.

358 *4.2. Barriers to Adherence*

359 Barriers to adherence are well documented in the literature ⁴⁸, particularly in relation
360 to adherence to medication regimes. This is reported in the MAM published in 2003¹
361 which, as previously discussed, provides a framework for understanding adherence.

362 Many of these barriers are also commonly seen in relation to splint wearing.

363 Kaskutas and Powell²⁷ reported that patients in their study had significant difficulty in
364 carrying out daily functional activities such as caring for their baby, cooking, and
365 working. Similarly, Savas and Aydogan³³ reported twenty-three different reasons
366 that participants gave for removing their splint in their questionnaire three weeks
367 post-surgery.

368 Given the poor adherence rates to medical intervention described by the WHO¹
369 (50% non-adherence) it is vital that clinicians try and understand potential barriers to
370 treatment. If clinicians understand these barriers, they then can have meaningful
371 conversations, and make patient-centred decisions about which treatment the patient
372 is most likely to adhere to.

373 **5. Limitations of this review**

374 There are a number of limitations to this present study. Firstly, our focus was solely
375 on studies pertaining to the treatment of the upper limb. However, further studies
376 relating to the lower limb and spine may also have yielded important information
377 regarding the measurement of splint adherence. Similarly, case series, and grey
378 literature were also excluded from this search, which may also have provided further
379 data. However, these exclusion criteria were necessary to provide a direct answer to
380 the specific question under consideration, and also to preserve the quality of data
381 assessment.

382 Furthermore, it was not possible to perform a meta-analysis of the results. In an ideal
383 scenario, our data synthesis would have included a direct comparison of study
384 outcomes. However, due to data heterogeneity this was not possible and therefore a
385 narrative synthesis was performed instead.

386 Finally, it is also true that the definition of the term 'splint' is not used uniformly in the
387 literature. Throughout this report, we have used the term 'splint' to reflect the
388 commonly preferred terminology of United Kingdom (UK) based hand therapists, but
389 it is possible that understanding of this has differs between the studies we included.
390 However, this was however mitigated against to some degree by the use of the
391 terms 'orthosis' and 'brace' alongside 'splint' in our search strategy.

392 **6. Conclusion**

393 This review demonstrates that the methods used to measure adherence and quantify
394 adherence in upper limb splinting following traumatic injury, are inconsistent. Several
395 methods have been presented, but all have limitations. Many studies in this review
396 rely on self-reported adherence data and although data collection is quick,
397 convenient, and cheap and regularly used in studies, it is however, well known to be
398 unreliable due to recall bias ⁴⁴. The use of sensors to measure adherence could
399 provide more quantitative and reliable data and is often seen as the optimal method
400 of measuring adherence as they provide objective continuous tracking of behaviour
401 ¹⁵, however this technology is in its infancy, and more work is required to increase
402 the reliability of these. Once reliable tools measuring adherence have been
403 developed, researchers then need to establish an agreed classification system to
404 categorise someone as being adherence or non-adherent to an upper limb splint
405 following trauma.

406

407 For clinical trials studying a splint or medical device, it is essential that researchers
408 are confident that participants are using the prescribed splint as advised. Being able
409 to measure adherence and accurately classify adherence raises this confidence and
410 ensures data rigor.

411

412 This review has also covered the barriers to splint adherence. If researchers and
413 clinicians can understand the barriers to splint adherence, and aim to mitigate these
414 barriers, patients and participants are more likely adhere to the splint provided. As
415 improved adherence is linked to better health outcomes and decreased health
416 utilisation¹, this is of utmost importance.

417

418 Ultimately, being able to measure and understand barriers to splint adherence will
419 enable researchers to conduct high-quality trials and allow clinicians to make patient-
420 centred decisions around splint prescribing. Therefore, further research is needed to
421 establish robust methods to measure and classify adherence and identify the
422 barriers to splint adherence.

423

424 **Declaration of conflicting interests:** EB is Chief Investigator, AD Co-Chief
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