**A randomised trial of detailed written consent compared to standard verbal consent in routine orthopaedic trauma**

Version 5

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SYNOPSIS

Protocol title: A randomised trial of detailed written consent compared to standard verbal consent in routine orthopaedic trauma

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**Summary**

Study title: A randomised trial of detailed written consent compared to standard verbal consent in routine orthopaedic trauma

Protocol version: Version 5

Objectives Primary objective: To assess whether patient post-operative recall improves when provided with a detailed method of informed consent

 Secondary objectives: a) Recruitment rate for a definitive trial b) To determine a clinically important difference of patient peri-operative anxiety c) To determine what procedural aspects met expectations d) Determine markers for poor patient recall.

Study design Multi-centre, randomised, controlled, parallel, comparative feasibility study. The study will be conducted at two teaching hospitals within the South Eastern Sydney Local Health District (SESLHD): St George Hospital and The Sutherland Hospital.

Planned sample size A total of 50 patients will be recruited over the allocated 6 month time period (March – September 2021).

Selection criteria

The inclusion criteria for this study is: (i) ≥18 years of age; (ii) patients with confirmed distal radius, ankle, femoral shaft, tibial shaft (lower limb long bone fracture), distal femur or proximal tibia fractures; (iii) able to speak and read the English language; (iv) capacity to make health care decisions independently; and (v) willing to participate in the trial.

Patients will be deemed ineligible if they: (i) medically diagnosed with cognitive impairment, including dementia; (ii) have limited literacy; (iii) poor or no understanding of the trial; (iv) in a critical medical condition; (v) require very urgent surgery (prioritised within 8 hours of presentation) vi) return to theatre for a surgical site infection

Study procedure Patients admitted for routine orthopaedic trauma will be screened for eligibility by the researcher at baseline. The patient’s medical records will be read to identify cognitive impairment and English proficiency. If paper medical records are not available Powerchart will be used to determine eligibility. Eligible patients will be recruited as inpatients pending orthopaedic trauma surgery at one of the two participating centres: St George Hospital and The Sutherland Hospital. Eligible patients will be invited to participate in the study by the researcher. Written consent to participate in the study will be obtained from all recruited patients after their surgery and after verbal consent is obtained by the surgeon. Time between arrival at ED and surgery differs with each case, but the approximate timeframe is 24 hours. Recruitment will be conducted between March 2021 and September 2021.

Statistical considerations This is a feasibility study, it will include measurement of feasibility and recruitment rate of eligible patients, and will therefore inform the sample size calculation of a definitive trial. A total of 50 patients will be recruited over the allocated 6 month time period (March – September 2021).

Statistical Analysis This study will be conducted by the intention-to-treat (ITT) principle. Missing data will be treated with a sensitivity analysis using multiple imputation. Means (±), standard deviation (SD) and confidence intervals (CI: 95%) will be used to present all continuous variables. A Mann-Whitney U test (p= < 0.05) will be calculated to determine difference between the control and intervention groups. Absolute numbers with percentages (%) will be used to present all binary variables. Chi-square test or Fisher’s exact test will be used to determine difference between the control and intervention groups. P-values of < 0.05 will be considered statistically significant. All analyses will be done in STATA Version 12.

Duration of the Study: 6 month time period (March- September 2021)

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1. **Introduction**
	1. Synopsis

**Background:** In routine orthopaedic trauma it is a requirement to consent the patient before they undergo surgery. In trauma settings the severity of the injury and time constraints can impact the informed consent process, thus leading to a poor patient understanding. This study proposes two interventions in which healthcare information can be delivered. The standard method involves the usual practice of verbal consent with an opportunity for the patient to ask questions. The detailed method will use a written information consent tool, aided by figures, in addition to procedural details, such as complications, benefits and alternative therapy. In both methods it is critical for the treating surgeon to provide the information in a manner that safeguards their ability to make an informed decision. Studies evaluating patient informed consent for trauma injuries agree on the importance of delivering comprehensible information 1-4. In emergency contexts the provision of comprehensible information can be executed poorly due to patient distress, time constraints, physical pain and ability to understand the material, leading to poor patient recall on procedural details 2,5. Patient recall can be optimised through the utilisation of detailed written information and visual aids.

**Question**: Does the use of written information consent tools improve patient recall and affect anxiety levels in routine orthopaedic trauma patients?

**Objectives**: *Primary*: To assess whether patient post-operative recall improves when provided with a detailed method of informed consent (use of a consent tool) *Secondary*: a) Recruitment rate for a definitive trial b) To determine a clinically important difference of patient peri-operative anxiety c) To determine what procedural aspects met expectations d) Determine markers for poor patient recall.

**Study plan**: *Design:* Multi-centre, randomised, controlled, parallel, comparative feasibility study. The study will be conducted at two teaching hospitals within the South Eastern Sydney Local Health District (SESLHD): St George Hospital and The Sutherland Hospital. *Outcomes:* Patient recall score (post-operative at 72 hours), HADs (pre-operatively and post operatively at 72 hours), Patient satisfaction score (post-operative at 72 hours), recruitment rate (6 months) and VAS pain score (pre-operative and post operatively at 72 hours). *Methods:* The study will include eligible patients with confirmed distal radius, ankle, femoral shaft, tibial shaft (lower limb long bone fracture), distal femur or proximal tibia fractures. Patients will be randomly allocated into two intervention groups: (i) detailed method of informed consent (use of information consent tools with embedded figures); or (ii) standard method of consent (usual verbal consent with opportunity to ask questions).

**Importance of proposed study:** Evidence suggests that the informed consent process is conducted poorly in trauma settings, leading to poor patient recall and misunderstanding on the procedure they have undergone. This study will examine the comparison between detailed and standard methods of informed consent in an orthopaedic trauma context. The selected participating centres are leading trauma and emergency hospitals within SESLHD with extensive caseloads. This study will be pivotal in determining whether the informed consent process at St George Hospital and The Sutherland Hospital needs reform. Furthermore, this study will examine the effect of these different interventions on patient peri-operative anxiety and post-operative satisfaction.

**1.2 Background**

**Informed consent and importance in healthcare**

Informed consent is the process of communication between a patient and surgeon prior to receiving a medical intervention, leading to the patient’s authorisation to undergo the treatment 6-8. It is a prerequisite for patients to be consented prior to undergoing any surgical procedure. Surgeons are ethically and legally obliged to provide sufficient information on the specified intervention, including the relevant risks, benefits and other treatments available to the patient 7,9. The Department of Health report that informed consent reflects that the patient has been provided with adequate information, is capable of understanding this information and made an autonomous decision free from surgeon coercion. Furthermore, a patient must possess the capacity for decision-making and understand the potential consequences of undergoing the procedure 2.

Failure to obtain informed consent can lead to serious ethical and legal ramifications including: diminished trust between a patient and surgeon 10, inhibited patient autonomy 7, patient safety compromise 7 and ligitation 7,9. Mclean suggests that surgeons are often not adequately trained in how to deliver information in a manner that ensures absolute patient understanding. Poor delivery of procedure details can negatively impact patient education on the proposed surgery. Patients may misinterpret the information, and not comprehend the complications and limitations of the surgery, manifesting in legal and ethical issues.

**Informed consent in a trauma context**

*Epidemiology*

The process of informed consent is not always sufficient in busy healthcare settings, such as trauma services, which can lead to poor patient-centred care 11. The Australian and New Zealand Trauma Registry (ATR) reported that in 2017-2018 there were 8, 454 trauma injuries classified as ‘severe’, with road trauma accounting for 45% and falls 36% of these cases. South Eastern Sydney Local Health District (SESLHD) is constituted of many healthcare services two of which have high presentations of trauma injury patients. In 2014, St George Hospital had an estimated 1,800 cases of serious trauma injuries and an overall emergency department presentation of 66507 patients 12. Traumatic injuries that have met the trauma criteria, resulting in trauma management, has increased by 149% at St George Hospital since 1992 13. Sutherland Hospital has an average of 50, 000 emergency department presentations every year.

Traumatic injury in an emergency department can pose a challenge to the informed consent process. There are several factors that can contribute to inadequate consenting of the patient, including: unplanned hospitalisation, time constraints in theatre, physiological distress and extensive pain 2, 5. Orthopaedic trauma patients have a higher risk of subpar comprehension and post-operative recall on the information provided to them 14.

In Australia, the mean time for a patient to receive definitive care after a traumatic injury in 2017-2018 was 1 hour 27 minutes 15. Giving patients sufficient time to read a Patient Informed Consent Form is paramount for the understanding and recall on the information.

**Evidence on the practice of decision aids in trauma**

There is emerging emphasis on shared-decision making (SDM) in clinical practice as it protects the patient’s autonomy, values and wellbeing 7, 16. SDM is the ongoing communication between the surgeon and patient leading to a shared agreement on treatment options 17 and can safeguard patient/surgeon trust.

There are many different types of decision aids that are beneficial for trauma patients, including video, patient information sheets, websites and illustrations. Decision aids are defined as patient education mechanisms that are paramount for SDM. These may be particularly useful in trauma as patient engagement and recall can be increased 17, 18. The study conducted by Bhangu compared the effect of decision aids (leaflets) between orthopaedic trauma and elective patients (n= 175), and found that recall of complications significantly lower in trauma patients compared to elective patients (62% vs 22%, p<0.001). Furthermore, only 90% of trauma group were able to recall what type of surgery they received, whereas the elective group had perfect recall (100%) 1. Results from a recent systematic review indicates that the overall recall of information provided during consent, including the complications, type of surgery, diagnosis of injury, risks and benefit was lower in orthopaedic trauma patients compared to elective patients 2. Trauma patient comprehension was greater when patient education was reinforced by video during consent 2.

Previous studies have demonstrated the importance of using decision aids when consenting orthopaedic trauma patients for surgery 3,4. One randomised control trial (20) of patients requiring surgery for closed ankle fractures (n=48) revealed that the video group had greater recall than the verbal consent group in both initial (40.1% p=0.0002) and follow-up questionnaires (27.2% p=0.0139). Educational tools, such as information videos, are more beneficial for orthopaedic trauma patients with a lower education level than verbal consent 4. Lin (2018) found that in trauma-related debridement patients (142) the mean knowledge scores were greater in the video group (72.57 ± 16.21 (SD)) compared to the written consent group (61.67 ± 18.39 (SD)). Promoting patient education by utilising decision aids can also positively affect patient satisfaction 3.

**Importance of the proposed study**

In routine orthopaedic trauma there is minimal research conducted to examine the association between written vs verbal consent in orthopaedic trauma, especially isolated fractures. The proposed study aims to determine the effectiveness of written consent tools in trauma patients and delayed patient recall. Furthermore, the study will the address gaps in current evidence by assessing the impact of decision aids with pre-operative anxiety. There is a paucity of trials that consider anxiety scores at the time of decision aids. We aim to determine if using decision aids in trauma context overwhelms a trauma patient and prompts anxiety.

**2.1 Project Objectives**

2.1 Aims

The proposed study will aim to determine the effectiveness of standard informed consent vs use of detailed written information consent tool for adult routine orthopaedic trauma surgery.

2.2 Objectives

This feasibility RCT will aim to:

1. Estimate the target recruitment rate for a future definitive trial. The target recruitment rate of eligible patients is 75%.
2. Determine the clinically important difference of patient peri-operative anxiety measured within 24hours of study intervention.
3. Assess patient retention of information provided during the process of informed consent, including their understanding of the procedure. Patient retention will be measured post-operatively within 48 hours of the intervention.
4. Determine what procedural aspects met patient expectations and which did not.
5. Determine markers for poor patient recall.

2.3 Hypothesis

We hypothesise that the patients that are consented utilising the detailed written support tool will have greater overall post-operative recall on the procedural aspects provided during the detailed written informed consent process in comparison to the patients that receive the standard consent method. Secondly, it is estimated that a rate of 75% of eligible patients will be included in this study.

**3. Methods**

3.1. Study Setting

The study will be conducted at two accredited teaching hospitals with affiliation to The University of New South Wales (UNSW) within the South Eastern Sydney Local Health District (SESLHD). The two centres are St George Hospital, Kogarah, NSW Australia and The Sutherland Hospital, Caringbah, NSW Australia. St George Hospital is the leading trauma service within the SESLHD with a large trauma caseload.

3.2. Study Design

This study is designed as a multicentre, randomised, controlled, parallel, comparative feasibility trial. There will be two parallel arms: (i) standard informed consent and (ii) detailed written information consent tool.

3.3. Randomisation

*3.3.1. Randomisation Sequence*

Patients will be randomly allocated into the two study groups: standard informed consent and the written detailed information consent tool. The randomisation sequence will be computer generated and incorporated into an online computer program (RedCap).

*3.3.2. Allocation Concealment*

Allocation will use an online based system through RedCap, requiring a login and leaving a verifiable electronic trail. The randomisation sequence will therefore be concealed.

3.3.3. Blinding

The treating surgeon and researcher will not be blinded to the study group allocation. Blinding is not feasible in this study. If this study is proven feasible after a 6-month period (achieving target recruitment rate) then a definitive trial will be conducted with greater availability of resources, including additional researcher officers. Therefore, blinding of outcomes assessors may be achievable.

**4. Participants**

4.1 Inclusion Criteria

The inclusion criteria for this study is: (i) ≥18 years of age; (ii) patients with confirmed distal radius, ankle, femoral shaft, tibial shaft (lower limb long bone fracture), distal femur or proximal tibia fractures; (iii) able to speak and read the English language; (iv) capacity to make health care decisions independently; and (v) willing to participate in the trial.

4.2. Exclusion Criteria

Patients will be deemed ineligible if they are: (i) medically diagnosed with cognitive impairment, including dementia; (ii) have limited literacy; (iii) poor or no understanding of the trial; (iv) in a critical medical condition; (v) require very urgent surgery (prioritised within 8 hours of presentation) vi) return to theatre for a surgical site infection

4.3. Recruitment

Patients admitted for routine orthopaedic trauma will be screened for eligibility by the researcher at baseline. The patient’s medical records will be read to identify cognitive impairment and English proficiency. If paper medical records are not available Powerchart will be used to determine eligibility. Eligible patients will be recruited as inpatients pending orthopaedic trauma surgery at one of the two participating centres: St George Hospital and The Sutherland Hospital. Eligible patients will be invited to participate in the study by the surgeon who will explain, “*My name is \_\_\_\_ and I am a member of the orthopaedic team. Your xrays show that you have sustained a fracture of your \_\_\_\_\_\_\_, for which we are recommending an operation. We are conducting a study at the moment, which is comparing two different methods for telling you about your surgery. One method will involve a standard conversation with you, while the other method will also include detailed written information that you can keep. We don’t know which method is actually better and want to randomly allocate you to one of these methods, similar to “flipping a coin”. The two methods are very routinely used, and all your other treatment and surgery will be exactly the same regardless of which group you are allocated. We will ask you about your experience with your surgery about 3 days after you have your operation. You can withdraw from the study at any time and this will not affect any of your care. Would you like to help with this study?”.<<need to specify verbal consent to questionaires*
If the patient verbally consents to participation in the study, they will be registered using an online (RedCap) database and randomised using a computer generated sequence. The patient will then be conveyed their surgery information using their allocated method. We will ask the patient to complete a consent form for their surgery, and a consent form for the study, along with the study information sheet. The arm of the study the patient is allocated to will be documented at the time of verbal consent to participate in the study by the surgeon. Time between arrival at ED and surgery differs with each case, but the approximate timeframe is 24-48 hours. Recruitment will be conducted between March 2021 and September 2021.

4.4. Study flow diagram

**5. Interventions**

5.1. Standard Method (Control Group)

The standard method of informed consent will be the usual standard of care given to routine orthopaedic trauma patients. Before undergoing surgery, the treating surgeon will provide a verbal explanation of the procedure including: surgical complications, potential benefits, details of the injury and surgical management. The patient will then be provided with an opportunity to ask any questions about the surgery.

5.2. Detailed Method (Intervention Method)

This intervention will incorporate all the usual information and documentation required in the standard method of informed consent, which is required by the health service. In addition, it will also include the use of a detailed written information consent support tool, which has sufficient information on the procedure, including visual aids. The written information consent support tool utilised in this study will be adapted from the Queensland Health orthopaedic consent templates 19, including the: Fractured tibia, fractured forearm, fractured femur and fractured ankle informed consent templates. These consent forms are widely used within the Queensland healthcare system, and they are available online for reference and education. Furthermore, the visual aids utilised will be adapted from the Orthopaedic Trauma Association 20, an international education organisation, which strives to promote excellence in care to patients. Each written information consent support tool will be presented in patient friendly manner promoting patient engagement in the process. All modified written information consent support tools will include the following elements:

* The condition (e.g. distal radius fracture) with a visual aid to indicate injury location.
* The treatment (e.g. fixation with plates or nails) with a visual aid to give the patient a visualisation of how the injury will be managed.
* General risks and specific risks to be presented in dot point format to ensure the patient does not become overwhelmed with extensive reading. Figures of common risks, such as Deep Vein Thrombosis (DVT) and surgical site infections (SSIs), will be included so the patient is aware of foreseeable complications as a result of receiving the treatment.
* Alternative treatment options (e.g. stabilisation) with the use of a visual aid so the patient can distinguish the difference in these treatments.
* Risks of not receiving the treatment.
* Benefits of receiving this treatment.
* Declaration and patient authorisation to undergo treatment.

The treating surgeon will go through the written information consent support tool with the patient, allowing ample time for the patient to read the form and comprehend the information. The patient will then be provided with the opportunity to ask questions regarding the procedure and the treating surgeon will address any concerns. The patient will also be given a brief copy of the information to keep. << patient to be given the whole information sheet with images, not summary copy

**6. Outcome Measures**

All data will be collected by the researcher at two different time points: baseline/pre-operatively (≤ 24 hours of surgery) and on discharge (≤72 hours post operatively). Table 1 summarises the time point each variable will be collected. All questionnaires will be conducted on the ward at the participating centres - St George Hospital and Sutherland Hospital.

**6.1. Primary outcome**

The primary outcome measure is patient recall on the information provided by the treating surgeon during consent (standard or detailed method). This measure was selected as the primary outcome because patient recall is important for determining patient education and effectiveness of informed consent methods. Patient recall will be assessed using interviewer-administered questionnaire developed by the research team. Any incorrect answers will be recorded, however will verbally corrected for the patient.

**6.2. Secondary outcomes**

* Hospital Anxiety and Depression Scale (interviewer-administered, self-reported, validated questionnaire using a 4-point Likert scale) collected ≤24 hours pre-operation and at 72 hours post-operation (Zigmound) (Appendix 2.). If the patient has been discharged prior to the 72 hours they will be contacted via phone.
* Patient Satisfaction Questionnaire Short Form (PSQ-18) (patient-administered, self-reported, validated questionnaire using a 7-point Likert scale) (Marshal) collected at 72 hours post-operation. If a patient is discharged prior to the 72 hours the patient will be contacted via phone.
* Rate of recruitment of eligible patients into the study (enrolment of at least 75%).

Visual Analogue Scale (Pain score), a validated, self reported tool to measure a patients current pain level collected at ≤24 hours pre-operation and at 72 hours post-operation. Pain is rated on a scale of 0-10 where 0 is the no pain and 10 is extreme pain. If a patient is discharged prior to the 72 hours the patient will be contacted via phone.

**Table 1. Schedule of collection timepoints for each baseline, primary and secondary outcomes.**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Baseline/ pre operative (≤ 24 hours Pre-operation)** | **Discharge/ post operative (≤ 72 hours Post-operation)** | **Notes of measure** |
| Patient Demographics |  |  |  |
| Age (yrs) | X |  | Researcher will use data from patient medical records. |
| Sex (male/female) | X |  | As above. |
| Highest Level of Education (secondary/tertiary) | X |  | Researcher will ask the patient during recruitment. |
| English first language (yes/no) | X |  | Researcher will screen medical records prior to recruiting the patient. If more than one spoken language is documented the researcher will ask the patient at the time of recruitment. |
| ASA | X |  | Researcher will use the ASA recorded on the intra-operative anaesthetic report. |
| Primary outcome |  |  |  |
| Patient recall |  | X | Researcher will ask the patient to complete the questionnaire 72 hours after surgery, in person or via phone.  |
| Secondary outcomes |  |  |  |
| PSQ-18 |  | X | As above. |
| HADS | X | X | Researcher will ask the patient to complete the questionnaire at baseline in the 24 hours prior to surgery, and follow up again 72 hours post-surgery. |
| Target Recruitment | X |  | Recruitment target rate will be recorded as the number of eligible patients consented to the study regardless of lost to follow up or withdrawn consent.  |
| VAS Pain Score | X | X | Researcher will ask the patient to complete the questionnaire at baseline in the 24 hours prior to surgery, and follow up again 72 hours post-surgery. |

**7. Sample Size**

This is a feasibility study, it will include measurement of feasibility and recruitment rate of eligible patients, and will therefore inform the sample size calculation of a definitive trial. A total of 50 patients will be recruited over the allocation 6 month time period (March – September 2021). This is based on the current annual numbers seen at each hospital. St George current sees about 50 ankle fractures, 60 distal radius fractures and 50 tibial/ femoral shaft fractures. At Sutherland the numbers are 40 ankle fractures, 45 distal radius fractures and 30 tibial/ femoral shaft fractures. Based on these numbers we hope to recruit at least 50 patients as we have only a 6 month recruitment period for the feasibility study.

**8. Statistical Analysis**

This study will be conducted by the intention-to-treat (ITT) principle. Missing data will be treated with a sensitivity analysis using multiple imputation. Means (±), standard deviation (SD) and confidence intervals (CI: 95%) will be used to present all continuous variables. A Mann-Whitney U test (p= < 0.05) will be calculated to determine difference between the control and intervention groups. Absolute numbers with percentages (%) will be used to present all binary variables. Chi-square test or Fisher’s exact test will be used to determine difference between the control and intervention groups. P-values of < 0.05 will be considered statistically significant. All analyses will be done in RStudio 1.2.1335.

**9. Ethical Consideration**

This protocol will be submitted to the SESLHD Human Research and Ethics Committee (HREC) for ethics approval. The proposed study does not place any additional burden on participants both standard method and detailed methods. In the standard method intervention, all information provided by the treating surgeon is the usual standard of care, there will be no omission of required information on the surgical procedure. In the detail method intervention, the same information will be delivered to the patient however the presentation of this information will differ because there will be visual and written aids included on the written information consent support tool. The orthopaedic decision support tools are routinely used in interstate health systems, and written information is frequently provided in the private sector, and recommended for use by specialist colleges such as the Royal Australasian College of Surgeons. All surgical procedures are considered routine orthopaedic trauma management. Consenting the patient for surgery is the sole responsible of the treating surgeon, the researcher will have no active participation in this process. Patients will be free to withdraw their consent at any timepoint. This study can be considered greater than low risk even though both interventions are standard, there is no known additional risk of the proposed intervention, and there will be no change to the routine care provided to patients, it still proposes a new intervention and randomisation of patients.

9.1. Informed consent

All patients that agree to participate in this study will be required to sign a separate consent form prior to receiving an intervention (standard method or detailed method). The researcher will assume responsibility of obtaining informed consent.

9.2. Confidentiality and Privacy

Record Retention

Patient identity will be protected in all professional reporting of trial data, including reports, journal publications and presentations. All patient information will be de-identified and a study number will be assigned to each patient. Study documents, including recall questionnaire, HADS, PSQ-18 and VAS will include the study number not patient name or demographics.

9.3. Data Management and Record Retention

All data collected will remain in a secure office located in the Orthopaedic Research Institute, Research and Education Building, Kogarah. Access to this office is authorised only with St George Hospital identification swipe pass. Patient baseline demographics, recall questionnaire score, HADS score, PSQ-18 score and VAS scores will be collected using the online RedCap application- an online research software database application available via the University of New South Wales, and accessible using a smart device. Access to this database will be password protected and only provided to individuals involved in the study, with all access verifiable using an electronic trail. Where online access is not possible, data will be collected on paper and stored in patient files within the research office, before transfer to RedCap. Final de-identified data collection will be done in a password protected excel document which will be stored in a password-protected computer issued by the hospital, which only the research team will have access to. The patient’s consent to the research study will not be kept in the patient’s medical record. Their consent will be filed and kept in the secure office along with their other study documents. Consent to their surgery will be documented as normal standard of practice in the patient’s medical record. This will not be kept as part of the research study.

**10. Data Monitoring**

The researcher will meet regularly with the University of New South Wales (UNSW) project supervisor to monitor the progress of the trial. During these meeting all issues can be addressed and resolved, and ensure that the recruitment timeline is being followed.

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