COVER PAGE

STUDY PROTOCOL

Study:

An Integrated-Delivery-of-Care Approach to Improve Patient Outcomes, Safety, Well-Being After Orthopaedic Trauma

NCT Number:

NCT02591472

Document Date:

August 23, 2018

Protocol

1. Project Title:

An Integrated-Delivery-of-Care Approach to Improve Patient Outcomes, Safety, Well-Being After Orthopaedic Trauma

2. Investigator(s):

Heather K. Vincent**,** PhD (PI)	College of Medicine, Department of Orthopedics and Rehabilitation, Division of Research
MaryBeth Horodyski, EdD, ATC (Co-I)	College of Medicine, Department of Orthopedics and Rehabilitation, Division of Research
Kalia K. Sadasivan, MD (Co-I)	College of Medicine, Department of Orthopedics and Rehabilitation, Division of Trauma
Terrie Vasilopoulos, PhD (Co-I)	College of Medicine, Department of Anesthesiology, Division of Research
Jennifer Hagen, MD (Co-I)	College of Medicine, Department of Orthopedics and Rehabilitation, Division of
Andre Spiguel, MD (Co-I)	College of Medicine, Department of Orthopedics and Rehabilitation, Division of Oncology Trauma Trauma
Robert Guenther, PhD, ABPP (Co-I)	College of Public Health and Health Professions, Department of Clinical and Health Psychology, Division of Clinical Psychiatry

3. Abstract:

Background and Significance: Nearly 3 million people have serious injuries from falls, vehicle crashes, explosions or assault every year. Surgical results are often excellent, but many patients still develop emotional stress and have a poor quality of life. We and others have found that most patients do not feel that they were emotionally supported in the hospital to help them to cope with distress. We recognize that there are different ways to treat an injured person, with or without emotional support. We do not know however, how these two ways differ in helping patients reach the goals that are important for them, improve quality of care and safety. Getting physical function back and having good emotional heath are needed for a high quality of life and meaningful living. This research project will test how two different approaches of hospital care affect patients' feelings about their physical function, emotional well-being and satisfaction with medical care.

Study Purpose: We will test whether the Usual Care or Integrated Care (which is Usual Care plus emotional support, and education/information during the hospital stay) helps

patients feel better about their physical function and emotional well-being. We believe that patients will feel better about their physical function and emotional health with the Integrated Care approach over the long-term.

Study Description: Usual Care will follow all the highest standards for injury treatment. Integrated Care will include medical care and emotional support. Study Staff are trained to provide emotional support and teach patients the skills for goal setting, taking ownership of journey, establishing lifelines, mobilizing resources and reducing stressors. Questionnaires and hand grip strength will be collected at the hospital and at normal follow-up visits at weeks 2, 6 and 12 and months 6 and 12. Range of Motion will be collected starting at the 2 week follow up visit.

Study Population: Patients who come to the University of Florida Trauma Center for a serious musculoskeletal injury will be asked to participate. A total of 100 people, aged 18-85 years, who have received or will receive ≥1 surgical procedures for their orthopedic injuries, will be included. Any major bone fractures that impair mobility and/or participation in activities of daily living and self-care will also be included. Patients may not have a brain injury and may not be using medicines to control psychological illness.

Primary and Secondary Measures: The main study measures are the Patient-Reported Outcomes Measurement Information System (PROMIS) questionnaires of Physical Functional quality of life and Emotional Well-being. Secondary measures are functional measures (Lower Extremity Gain Scale, handgrip strength, range of motion of major joints) and psychological illness questionnaires, medical complications, rehospitalizations, and comorbid disease.

Analytic Methods: We will use specific tests to find out the differences between Usual Care and Integrated Care on our emotional well-being and functional outcome, and adjust results appropriately for missing numbers. Tests will be used to make sure that the study population represents other trauma populations. Participants will repeat all measures at outpatient follow-up visits during weeks 2, 6 and 12 and months 6 and 12.

4. Background:

Orthopedic trauma is an unforeseen life-changing event. Nearly 2.8 million Americans sustain traumatic orthopedic injuries such as major fractures or amputation each year.[1] Injury is treated in the hospital by physicians who medically stabilize and reconstruct the patient.[2,3] Upon completion of their hospital stay, patients are discharged to begin their reintegration back into home and community activities. Despite high surgical success and survivorship rates, these injuries often result in poor quality of life (QOL)-related outcomes in otherwise healthy people.[4] Fifty to ninety percent of patients develop severe psychological distress such as post-traumatic stress syndrome, depression or anxiety.[5–7] Patients are often not provided the comprehensive support care and resources that are necessary to cope successfully with psychological stress and reintegrate into purposeful living.[8] Our work corroborates that ≥85% of these patients do not receive any form of the psychosocial support that they need to cope with distress.[8] This is a major problem because high distress levels predict poor physical function, use of pain medications and low QOL.[9,10] Survivors often cannot return to work,[11] have persistent pain[12] and experience social isolation. Distress worsens the self-perceptions of functional gain and efficacy[13] and decreases personal fulfillment. Lingering psychological distress contributes to the development of other health problems[14,15] and rebuilding of life is negatively im-pacted.[1–3] The lack of psychosocial

support contributes to injury reoccurrence, injury recidivism[16] re-hospitalizations and longer hospitalization stays,[17] and higher personal and societal health care costs.[18]

Patients affected by psychological stress face enduring adversity in life[15] and have an increased incidence of costly and damaging sequelae,[14] including chronic pain[14] and comorbid disease.[15] Trauma populations with a significantly higher prevalence of distress disorders and related poorer functional QOL outcomes include non-white Hispanics,[19] African Americans[20,21] and the uninsured.[22] Female gender, poor socioeconomic status and low self-efficacy are predictors of the on-set of psychological illness after traumatic injury. Populations with these characteristics rarely receive psycho-social support and this contributes to poor functional outcomes, prolonged disability, low return-to-work rates and poor health-related QOL.[22]

Variations in the delivery of orthopedic trauma care exist. However, there is currently a lack of rigorous comparative efficacy research to determine which delivery approach produces greater improvements in the outcomes that are most desired by patients, specifically, functional QOL and emotional well-being. Without this evidence, patients are not empowered to participate effectively in their care and recovery. The proposed research is significant because it will directly compare these delivery-of-care approaches and measure the patient-reported outcomes that are considered important to patients. Currently, the usual-care approach to patients with orthopedic trauma focuses on the medical and anatomical stabilization of the patient. It does not, however, provide the simultaneous psychosocial and emotional support that patients need early in the care process to cope with psychological stress and understand the recovery process. This communication and support gap in care worsens the psychopathology of orthopedic trauma. The patient, *while receiving the latest medical care for the injury, does not receive the overall care needed to treat the entire person.* The Amputee Coalition and the American Trauma Society[4,14] and other national organizations support the need for addressing these treatment gaps. These organizations indicated that patient-directed research that emphasizes communication should be a priority for trauma centers.

A Unique Approach to Addressing the Problem. Our research team has used a unique approach to understand the patient experience and the factors that contribute to poor outcomes and safety concerns. We created the very first UF Trauma Patient Advisory Board, a group of survivors who have come together to help direct the research questions that we are answering. From the panel, we have identified that communication gaps in the delivery-of-care that can affect emotional well-being, and subsequently their patient experience and satisfaction. Patients have directly told us that their hospital stay could be improved with a delivery-of-care system that provides better communication, support and guidance on how to safely navigate the transition from hospital to home. We propose to enhance the patient experience in care by implementing an integrated-delivery-of-care approach, which provides simultaneous medical and psychosocial treatment for orthopedic-trauma patients. This will include a facilitator-driven *10-Step Program on Transformation After Orthopaedic Trauma (the Transform-10 Program)*, the steps of which will be personally provided to each patient. The key ingredient to this approach is communication. The content has been driven by patient input. Compared to the usual-care system, the integrative-care approach offers patients support they need to overcome orthopedic injuries through daily and open communication and discussion.[14] Improved communication between the patients and care teams can help reduce harm and prevent oversights from occurring. We will investigate how integrative care can improve patient experiences and satisfaction with care.

Significance of the Study: The contribution of this work is expected to have a positive impact on the treatment care of patients who have experienced orthopedic trauma and other populations for the following reasons: reduction of the personal and societal burdens associated with the injury, improvement of delivery-of-care systems to help survivors with serious health conditions cope with life hardships, improve safety, and empowerment of the family and caregivers in the medical care process.

Larger Impact of the Project: Compared to Usual Care, we anticipate that the Integrative Care approach will improve patient satisfaction and reduce safety risks. Both of these will translate to better emotional and physical outcomes, fewer complications and readmissions. Moreover, higher patient satisfaction lessens the number of risk management episodes and substantially reduces the number of malpractice suits.[23] Moreover, the effects on the hospital system could be significant as we can help identify patient safety concerns, optimize care processes and potentially reduce the need for medical services during recovery. From a global perspective, this study is directly aligned with the missions of the Affordable Care Act, and the findings may help improve care processes to meet the federal standards. It is the hope that the processes we propose here can help UF achieve the quality of care metrics that are important to the patient and to the federal agencies that support this institution.

5. Specific Aims:

Specific Aim 1: Determine whether Usual Care or Integrated Care is most efficacious with respect to producing better functional QOL in patients receiving care for orthopedic trauma injury.

Hypothesis: Based on our preliminary findings and others,[8,24,25] we hypothesize that Integrated Care will be more effective in producing better post-treatment functional QOL than Usual Care.

Specific Aim 2: Determine whether Usual Care or Integrated Care is most efficacious with respect to producing better emotional well-being in patients receiving care for orthopedic trauma injury.

Hypothesis: Based on our preliminary findings and others,[8,24,25] we hypothesize that Integrated Care will be more effective than Usual Care in producing greater emotional well-being after hospital discharge. This hypothesis is based on our work[8,26] and others[4,24,27] that demonstrate lower prevalence and severity of psychological distress with Integrated Care approaches compared to Usual Care in patients with orthopedic trauma.

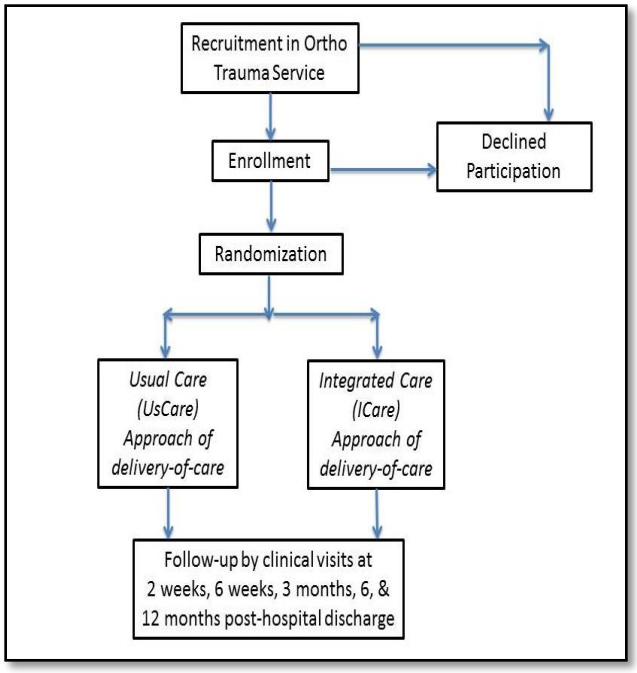
Specific Aim 3: Compare the prevalence of medical complications, rehospitalizations and comorbid disease out to six months after discharge.

Hypothesis: We hypothesize that the Integrated Care group will have fewer rehospitalizations, medical complications and comorbid disease will be present in the Integrated Care group compared to Usual Care. Satisfaction with medical care will be higher in the Integrated Care group.

6. Research Plan:

Research Design: This is a single-blinded, randomized controlled study in which the research and care teams, including the physicians, will know which patients will receive

the integrated medical care or standard medical care.[28] We will execute this study under the Consolidated Standards of Reporting Trials Statement [28] for randomized controlled trials with the Patient Reported Outcomes extension.[29] There are two arms to the study, an Integrated care (ICare) arm and a Usual Care (UsCare) arm. Figure 1 (following page) provides the study flow diagram for this study. After discharge from acute care, the patient will return to the outpatient orthopaedic trauma clinic for regular follow-ups. The study team will minimize the patient burden by collecting data at the normal outpatient visits at weeks 2, 6, 12 and months six and 12. Patients will be asked for email addresses so that surveys may be emailed out, if the patient prefers. Therefore, patients may complete the surveys at home prior to their follow up visits. This will be based upon patients' preferences and resources.



Patient Sample: Patients will be recruited after admission to the University of Florida's Orthopaedic Trauma service at UF Health at Shands Hospital. The study team will determine using observation whether the patient is lucid (able to understand and recall information if medicated) at the time of approach. If not, the team will wait until the patient is able and willing to hear about this study.

Inclusion Criteria:

- Patients admitted with severe or multiple orthopedic trauma
- Aged 18-85 years
- Who have received or will receive ≥1 surgical procedure for their orthopedic injuries
- Any major bone fractures that impairs mobility and/or participation in activities of daily living and self-care

Exclusion Criteria:

- Aged <18 or ≥85 years
- Have a traumatic brain injury
- Have an inability to communicate effectively (e.g., at a level where self-report measures could be answered completely; such as medicated state or mechanically ventilated)
- Currently using psychotropic medications
- Have psychotic, suicidal or homicidal ideations.

Randomization Process: The randomization process will be performed using a random number table and recorded separately into sealed envelopes. These envelopes will be randomly placed into patient folders. After the informed consent process, facilitator will open the randomization envelope. The patient will not know what group they have been randomized to, only the facilitator and study staff will know which group the patient is in. ..

Facilitators: The facilitators are an integral part of the study team. They have all of the proper training (IRB, HIPPA, NIH, etc.) to work with patients in health care and research settings. The Facilitators will be responsible for administering the surveys to collect the data on emotional well-being. The facilitators will also be familiarized with administering the *Transform-10* Program. The facilitators are supervised by the attending orthopaedic trauma physician (Dr. Sadasivan or Dr. Hagen), Dr. Horodyski, and a clinical psychologist, Dr. Guenther. Dr. Guenther, Drs. Sadasivan and Hagen, and Dr. Horodyski will also serve as mentors for the facilitators as questions arise regarding the implementation of the *Transform-10 Program.* The facilitators will make daily rounds with the trauma physician and other daily visits during the patients' hospital stay to ensure they are adhering to their treatment plan and to clarify any details about the patient's injury or treatment plan. The facilitators will serve as liaisons between the hospital staff, physician, clinic staff, and discharge planner. These individuals will be in daily communication with the study team, physician, and/or other hospital personnel to ensure patient safety and that the patients' medical questions are presented back to the attending physicians. Daily monitoring of facilitators by the attending orthopaedic trauma physician and study team will occur via morning conference prior to meeting with patients and a debriefing with the study coordinator at the conclusion of each day.

Study Groups: The ICare will be compared to UsCare. This choice of comparators was made for several reasons. UsCare for orthopedic trauma involves surgical intervention, acute care therapies, post-acute rehabilitation and follow-up clinic visits after discharge. Psychosocial support and resources are commonly provided after discharge, but only if needed. ICare provides the simultaneous provision of psychosocial support and medical care beginning at admission to the trauma service. After hospital discharge Both study groups will be asked to come to the Human Dynamics Laboratory/Sports Performance Center at the Orthopaedic and Sports Medicine Institute (this building is where they will have follow up visits with their physician) about an hour early to complete the functional assessments and questionnaires. For the ICare group, the remaining steps for the *Transform-10* Program will be reviewed within this time. After the assessments and questionnaires, the participant will be escorted to the clinics on the second floor to see the physician.

1. Usual Care (UsCare)*.* Post-operative care is based on widely-accepted recommendations[8] and on the current understanding of injury treatment. The key components of the care system include medical stabilization, injury repair, discharge planning and physical rehabilitation. Usual Care includes radiographic imaging and administration of pain medication and antibiotics, skin care and range of motion of the injured area. The attending physician visits with the patient a minimum of once per day and the nursing staff attends to patient care approximately once every four hours. Upon admission to acute care, the attending physician (*Dr. Sadasivan or Dr. Hagen*) will introduce the team to the patient and explain the purpose and activities involved in the medical approach. The patient will have the ability to ask questions and express concerns. Each patient will be assigned a Facilitator who will have contact with the patient. All medical processes will proceed under the guidelines of Usual Care. The Facilitator will visit the patient when the Attending Physician performs rounds only. If applicable, the Clinical Psychologist (*Dr. Guenther/ Postdoctoral Fellow*) will review patient concerns and issues as presented to him by the Attending Physician. The initial measures will be obtained in the hospital setting, and follow-up measures will be collected in the typical outpatient times out

to twelve months depending on the patient's clinical care plan. The UsCare group will get all of the materials that make up the *Transform-10* Program at their 12 month follow up visit. Following their final data collection, the facilitator will briefly review the Transform-10 Program (ten steps) with the patient and address any questions that the patient has.

2. Integrated Care (ICare). The Integrated Care approach provides Usual Care processes plus simultaneous psychosocial support via the *Transform-10 Program*. Integrated Care was consolidated using the direct guidance of our Patient Advisory Panel, Partners and practitioners who care for trauma patients. We have identified psychosocial components and resource content to help patients focus on the positive and productive pathways necessary to cope with stress and achieve a high QOL. These key components can be adapted for different hospital settings, geographical locations and available resources when implemented in a larger scale. Content of the Integrated Care was based on patient needs, previous outcomes research and techniques advocated by our Partners. This delivery-of-care system format and the transformative skills that are taught will provide the patients the information and resources they need to help them reintegrate back into home, community and work activities. These steps may also improve quality of care and improve patient safety. Trained 'Facilitators' will be trained to administer the *Transform-10 Program*. These Facilitators have a background in related health fields such as licensed athletic trainers.

Through the use of a centralized folder, the *Transform-10* Program will include information regarding emotional well-being, social support, and provides opportunity for the patient to openly discuss their thoughts and concerns regarding their recovery. The steps will initially be reviewed with the patient by the Facilitator(s) on the trauma floor at the hospital as it is convenient for the patients. If the patient is alert and willing to review the steps, the facilitator will spend about 10-30 minutes with the patient depending on the patient's questions, concerns, and physical state. Not all steps will be reviewed at one time. The facilitators will be aware of the patient's state and timing of delivery of the *Transform-10* Program. The goal is to review steps 1-7 during the patient's hospital stay and the remaining steps will be covered at follow-up visits with the physician. If steps 1-7 cannot fit into the patient's hospital stay, these steps will simply be covered at follow-up visits. If previous steps covered during the hospital stay need to be reviewed, the steps will be reiterated at follow up visits. The patient's normal clinical care usually includes a hospital stay, a 2 week follow up, 6 week follow up, 12 week follow up, 6 month, and 1 year follow up visit. Therefore, these steps will be covered over the time of their recovery and care plan. Lastly, patients within this group will receive a structured, physician-approved exercise program at follow-up visits to promote movement and strength prior to beginning supervised physical therapy. The steps of the *Transform-10* program are shown in Table 1 below[30–35,27,36–38]:

Table 1. Integrated Care (*Transform-10 Program*): A communication-focused program of ten key steps to personal transformation after orthopaedic trauma.

Step	Process
1. Become a survivor	Move from a mindset of being a "victim" to one of being a survivor; express feelings about trauma and move forward positively.
2. Go all out for recovery	Find things that you are grateful for and appreciate goodness in others and oneself; think of this time as an opportunity to self-improve. Make your environment safe around you while you recover.

3. Movement is life	Conscious thought about and participation in motion improves recovery; celebrate progress in any motion, no matter how small or large. Higher mobility levels are related to greater societal participation and QOL. Better function improves physical safety during recovery.
4. Set goals for recovery	Contemplate the question, "*What gives my life meaning*?" Break up the rehabilitation process into small increments to make the recovery process manageable, measurable and controllable.
5. Take ownership of your journey	Seize responsibility and take charge of your recovery to achieve goals. This provides daily purpose and increases self-efficacy. Develop resilience. Draw a 'care map' for you and your recovery. Adhere to safety plans from your doctor.
6. Establish lifelines with others	Use the "buddy system". Rely on a non-family member to be an objective soundboard to help deal with possible physical and psychological setbacks.
7. Mobilize all resources	Mobilize and access free resources. Sunlight, fresh air and free outdoor activities (stage-appropriate exercise) are essential to helping the body and mind recover from trauma.
8. Rally your social support	Bring family and friends together to assist in recovery.
9. Take steps to return to normal	Keep life activity patterns (sleep, diet, exercise) and body rhythms as close to normal as possible.
10. Reduce available stressors	Replace avoidable stressors with positive thoughts and activities such as mindfulness, relaxation and imagery reduces flashbacks and stress.

Data collection and Measurements: The study team will follow a systematic process for data collection. Each patient will have a folder of electronic case report forms on the REDCap repository. Form design will follow *Good Clinical Practice* rules. Within each patient folder, there will be a study checklist. When electronic case report forms are completed, REDCap updates the status to indicate 'completion'. Data will be validated at the time of input by computerized controls that ensure the validity and quality. REDCap contains system integrity measures to guarantee the integrity of the system and to protect against data loss. On a weekly basis, all records will be reviewed by the Facilitators and the Clinical Coordinator.

***Patient-Reported Outcomes*.** Patient-reported outcomes will be primary measures of the study. Patients are the most important source of information regarding the outcomes of interest, because this study focuses on patient perceptions of functional QOL and emotional well-being. At study entry, all patients will be asked to complete surveys with a Facilitator. The combination of proposed subjective and additional objective measures will create a complete picture of the patient experience.

1. Functional QOL: PROMIS™ was developed to help generate standardized, valid and precise perceived measures of QOL for use in clinical research using recent measurement theory, or item response theory. PROMIS™ item banks administered using Computer Adaptive Test provide a more precise measure of QOL in both the upper and lower thresholds of the measure and reduces patient burden.[39] Recent testing of PROMIS™ domains has been performed in patients with various upper and lower body orthopedic trauma injuries, with specific emphasis on Physical Health. Importantly, the items within the PROMIS™ domains (ability to perform self-care, activities of daily living, instrumental

activities of daily living, feelings of distress, satisfaction with social activities and meaningful participation in life activities) are specific to concerns raised by our patients.

***2. Functional Ability*:** Objective clinical measures of functional gain will complement the patient-reported outcomes The attending physician and care team normally perform a series of clinical tests to determine the initial functional status of each patient at admission and during recovery to track functional progress. Valid, reliable upper and lower body functional tests were selected that reflect the ability to live independently.

- ***Handgrip Strength**:* [40] Isometric handgrip strength is a valid predictor of mobility and QOL, and will be measured using a hand-held hydraulic dynamometer.[41] Handgrip strength is clinically important as it strongly predicts long-term function capability after orthopedic trauma.[41] The ICC for handgrip strength testing is 0.95.
- ***Lower Extremity Gain Scale (LEGS)**:* [42] LEGS consists of a 3-meter walk, putting on a sock, putting on a shoe, rising from an armless chair, stepping up and down stairs, getting on and off the toilet, reaching from a sitting position to an object on the ground. In people with traumatic fractures, LEGS has high internal consistency and the content, concurrent and construct validity are high.[42] The clinical relevance of better physical function and ambulation scores is a reduced risk of infection, delirium and prolonged hospital stay.
- ***Range of Motion (ROM):*** Establishing early and appropriate AROM within and at the joints above and below the injury site in the subacute/pre- structured physical therapy phase is significantly correlated[43] with increased functional outcomes.[44] The use of active range of motion (AROM) as a measure of functionality is common across multiple disciplines, including orthopaedics, physical therapy, and athletic training. Use of goniometer and a digital inclinometer to assess AROM have been validated.[45] For the present investigation a digital inclinometer will be utilized to measure AROM of all joints and ROMs of interest. Lower extremity range of motion will be collected for hip flexion; knee flexion/extension; and ankle plantar/dorsiflexion. Upper extremity range of motion joints will include shoulder flexion/extension, abduction, and internal/external rotation; elbow flexion/extension; wrist flexion/extension.

***3. Emotional Well-Being*:** PROMIS™ measures of perceived well-being will include the Psychosocial Illness Impact Positive, Satisfaction with Social Roles and Activities, and Anxiety, Depression.

5. Medical Complications, Rehospitalizations and Comorbid Disease:
Electronic medical records will be used to obtain information on patients, including sociodemographic and socioeconomic characteristics, trauma injury type and severity, location and additional soft-tissue injuries. If applicable, information about the nature of the trauma will be obtained including issues that may have precipitated their orthopedic injury (e.g., drunk driving, drug use, if other individuals were injured/ killed in the accident). Additionally, Computed Tomography (CT) Scans of the thigh and abdomen, which are ordinarily obtained for orthopaedic trauma patients, will be examined to calculate visceral, intramuscular, subcutaneous adiposity, and fat free mass. Increased adiposity in these regions has been linked to decreased functional ability and recovery, as well as decreased long-term mortality.[47,48]

The prevalence of medical complications, rehospitalizations and comorbid disease will be captured in two ways: 1) using data extraction methods from the electronic medical records, and 2) directly from patients during their follow-up visits in the outpatient clinics. The number of readmissions (and length of the readmissions), reasons for readmissions, the number and type of complications will be collected. The onset of new comorbid diseases, with particular emphasis on psychological illnesses, will also be collected using these following tools that have been validated for use in the trauma population:

- ***The Posttraumatic Stress Disorder (PTSD)*** *Checklist* will be administered to measure posttraumatic stress levels. The PTSD Checklist has high temporal and internal consistency and high content validity.[49]
- ***The Beck Depression Inventory*-II[29]** is a broadly-applicable, clinically relevant psychometric instrument with high reliability and consistency.[50] BDI-II has high capacity to discriminate depressed and non-depressed people.[50]
- ***The State-Trait Anxiety Inventory (STAI*)** will be used to measure state anxiety (anxiety about an event) and trait anxiety (anxiety level as a personal characteristic). Internal consistency ranges from 0.86 to 0.95, with considerable evidence of the construct and concurrent validity of STAI-II.[51] STAI values correlate with negative outlook of self and their current experience after traumatic injury.[52]
- ***Pain-Related Fear:*** Kinesiophobia is the psycho-social, somatosensory neuronal feedback, manifestation of fear of movement due a belief it will induce pain or injury.[53,54] To assess the pain-related fear in orthopaedic trauma the Tampa Scale of Kinesiophobia-11 (TSK-11) will be used (α=0.79, ICC=0.81).[54]

  6. Research Quality: Exit Survey about patient perceptions of research and subject interactions.

We hypothesize that the Integrated Care group (with the Transform 10 Program) will have fewer rehospitalizations, medical complications and comorbid disease will be present in the Integrated Care group compared to Usual Care.

Complications and Safety Events: A structured safety monitoring system will assure real-time participant care and unbiased monitoring of safety. A summary of complications and safety events will be reported by the Study Coordinator. For ongoing participant safety, events will be assessed by the PI, physician, and Co-investigators to determine if they are Serious, Unexpected or On-site. If so, an event evaluation form will be completed that will include a description of the event, a classification of seriousness, assessment of potential relationship to the study, assessment of need for change in the consent or the study activities, a summary of known prior health issues, event outcome and a classification of the main organ system involved. Participants will be instructed to talk with the study team about any discomforts that occur during the study whether they believe the discomfort is related to the study or not. All patients will be monitored 24 hours a day, 7 days a week while in the acute care service. Should any abnormal physiological response occur (e.g., abnormal heart rhythm, dizziness) the Attending Physician (*Dr. Sadasivan*) will be alerted to mobilize the appropriate safety response.

Statistical Analysis: The Statistical package for the Social Sciences (SPSS, v 22.0; Chicago, IL) will be used for analysis. Descriptive statistics will be calculated on

categorical study variables and demographics (means and standard deviations for continuous variables, frequencies and percentages for categorical variables). Chi-square for frequency distributions will be used for patient satisfaction to test main effects of time and treatment and their interaction, on patient satisfaction; however, because patient satisfaction will only be measured at the end, a standard general linear model will be used. The primary analyses for all aims will utilize a mixed model repeated measures approach. These analyses can assess the main effects of treatment and time on outcomes, as well as their interaction (treatment x time). Specifically, independent variables will include care approach (integrated vs standard) and time point (admission, 2 weeks, 6 weeks, 3 weeks, month 6, and 12 months). Dependent variables will include all functional measures (actual and perceived). Mixed models are the preferred approach to analyze data with repeated measures; these models can account to for correlation among repeated measurements, flexible time effects, and can handle missing data. Significant interactions between treatment and time would indicate that the change in the outcomes (i.e. slope) was dependent on the patient's treatment group. If a significant interaction is identified, the Preacher method will be used to estimate the magnitude and direction of the interaction. A p value will be established á priori at <0.05 for all statistical tests. Continuous data that are not normally distributed will be transformed prior to analysis. Appropriate multiple testing corrections will be performed to limit Type I error.

Sample Size: A sample size of 100 was determined in an *a priori* manner using G*Power software program.[55,56] Anticipating that the study population will be younger but otherwise similarly distributed as that of Zimmerman et al.[42] the sample size, N=100, was determined to be sufficient to have a medium effect size (Cohen's d=0.60, power of 0.80, and alpha of 0.05). This then translates into variable detectable mean differences depending on the outcome. For example, a 6.4 point difference in the State Trait Anxiety Index (STAI; one of the psychological measures for the study) can be detected assuming a standard deviation (SD) of 10.0; for AROM a 8.3 difference with an 12.0 SD. Linear mixed effects models will be used to analyze differences between UsCare and ICare in continuous outcomes.[57] Fixed effects will include randomized treatment group, time of measurement, baseline measurement, and covariates. An interaction term between treatment group and time will be modeled to assess how longitudinal changes in the outcomes differ between treatment groups. Subject-specific effects (random effect) will also be modelled to account for intra-individual correlation across measurement occasion. For categorical outcomes, a similar approach will be employed using generalized linear mixed models with a logit-link function (i.e. mixed-effects logistic regression)**.** Sensitivity analyses will compare the impact of different covariance structures underlying the repeated measurements (e.g. unstructured, autoregressive,[58] and compound symmetry) on the results from the mixed-effects models.

7. Possible Discomforts and Risks:

Consent: Written informed consent will be obtained after explanation to participants about all procedures and time commitments. The team members will explain to prospective participants the purpose, methods and extent of the study. Potential participants will be asked to read the informed consent form and to ask questions.

Confidentiality: There is the potential minor risk of breach of confidentiality of information

Stress: Patients will not experience greater risks if randomized to one care approach over the other. The measures that will be conducted during the study include PROMIS instruments, surveys and brief functional tests (handgrip strength, ROM, LEGS functional measures). The risks to performing these patient reported outcomes and functional tests are very low. Although a minimal risk, completing surveys may cause stress to some participants who may believe that they are not providing correct answers to the study team. The survey questions have a very low psychological risk if participants are upset by questions that ask them to think about their own poor health or problems that are disturbing. Should a patient present, answer, or score in particular negative manner on the psychological measures we have implemented, a Distress Referral Protocol for the patient's safety. This protocol states that patients scoring one standard deviation above the normative range for this patent population will receive further evaluation by the clinical psychology service.

Physical Discomfort: Potential minor discomforts of some of the functional tests can include transient muscle soreness for all patients, whether in the study or not. Muscle soreness may occur when participants begin moving again after injury. This symptom is common following unaccustomed physical activity, and the duration of this soreness is generally up to 48 hours after the activity.[59] The study team members will explain this potential risk to all participants to minimize this stressor.

Protections Against Discomforts and Risks:

Consent and Confidentiality: Potential participants will be asked to read the informed consent form and to ask questions. The form will be written in simple, easy-to-understand language. We require the coordinator to review all key aspects of the study verbally. They will then question potential participants to ascertain whether they have understood the information. A copy of the signed and dated consent form will be given to participants, and the original document will be placed in subjects' individual study files, which will be stored in a locked, secure location in the OSMI (room 1135).

Stress: The study team will assure all patients that there are no "correct" answers on their survey responses. The Study Coordinator or Facilitators will be present at all times during data collection to help answer any questions that may be confusing. The survey questions have a small likelihood of low psychological risk if participants are upset by questions that ask them to think about their own poor health or problems that are disturbing. Participants are free to refuse to respond to any question that they believe may result in psychological disturbance.

Protection of Personal Health Information: Data will be used only in aggregate and no identifying characteristics of individuals will be published or presented. Confidentiality of data will be maintained by using research identification numbers that uniquely identify each individual. Safeguards will be established to ensure the security and privacy of participants' study records. Appropriate measures will be taken to prevent unauthorized use of study information. Data other than demographic information do not use names as an identifier. The research ID number will be used. The research records will be kept in a locked room in the OSMI. The files matching participants' names and demographic information with research ID numbers will be kept in a separate room and will be stored in a locked file that

uses a different key from that of all other files. Only the study team members will have access to these files, and they will be asked to sign a document that they agree to maintain the confidentiality of the information. After the study is completed, local data will be stored with other completed research studies in a secured storage vault within the OSMI.

Distress Referral Protocol: We acknowledge that for some patients, the level of psychological distress is beyond the capability of this program to provide the support necessary. In these cases, we will enact a Distress Referral Protocol. When a patient is identified as displaying evidence of elevated distress, a member of the care team will ask the patient to complete the BDI-II and STAI surveys, and then they will interview the patient about the evidence of distress. Patients, who have test scores greater than one standard deviation from the normal score, will be referred for further evaluation by the Psychology Service via the electronic medical record (EPIC) referral process.

The Psychology Service will consist of Dr. Guenther assisted by graduate students, interns, and/or postdoctoral fellows in the Department of Clinical and Health Psychology at UF. Trainees on that service will be directly supervised by Dr. Guenther. Those services will include a formal clinical interview, development of a diagnostic conceptualization, development of a treatment plan, and provision of treatment designed to reduce the patient's distress and improve coping. Treatment will usually consist of cognitive-behavioral interventions with strong scientific support for their efficacy. The BDI and STAI may be re-administered periodically to assess level of improvement after treatment has been initiated. Psychological treatment visits can be reduced in frequency or stopped following sufficient decrease in patient symptom scores and perceived distress.

Data Safety and Monitoring Plan.

A Data and Safety Monitoring Plan (DSMP) will be implemented to ensure the safety of all participants involved in the study and to ensure the validity and integrity of the data. The PI with the advice and assistance of the study team will monitor all aspects of safety. The Study Coordinator will meet monthly with the PI to review all Serious, Unexpected and On-site adverse events. Within 24 hours of initial confirmation, the PI will complete an Event notification and Evaluation form for all Serious, Unexpected and On-site adverse events which will be reviewed by the IRB. Non-serious event tracking will be monitored using the Health Events Questionnaire data collected following the running protocol. A summary of these non-serious events will be reported to the PI and IRB. A structured safety monitoring system will be established in order to both assure real-time participant care and unbiased monitoring of adverse outcomes. For ongoing participant safety, events will be assessed by the PI, physician, and Co-investigators to determine if they are Serious, Unexpected or On-site. If so, an event evaluation form will be completed that will include a description of the event, a classification of seriousness, assessment of potential relationship to the study, assessment of need for change in the consent or the study activities, a summary of known prior health issues, event outcome and a classification of the main organ system involved. The classification of potential relationship to the intervention is as follows.

Definite - Temporal pattern + Known or expected AE response pattern

Probable - Temporal pattern + Known or expected AE response pattern + Could not be explained by participant's clinical state

Possible - Temporal pattern + Known or expected AE response pattern + Could have been produced by a number of other factors

Unknown - Relationship for which no evaluation can be made.

Not related - AE for which sufficient information exists to indicate that the cause is unrelated to the study intervention

The study PI and Co-investigators will notify the IRB of any serious adverse events that result in death or additional medical care within 24 hrs. The PI, Dr. Heather Vincent, can be reached at 352-273-7459.

8. Possible Benefits:

There is no direct benefit to any of the patients whose data are used in this study. However, there are indirect benefits of the analysis of these data. The study team completed research to determine what outcomes are important to patients who are receiving care after orthopedic surgery. Identification of common patient experiences and concerns helped to shape our research questions on the outcomes important to patients and caregivers. This is significant because we can effect meaningful change in how patients are managed during their hospital stay and beyond.

Analyze the risk-benefit ratio: This study poses relatively low risk to individuals. It poses a low risk of breach of PHI. The possibility of identifying processes that can improve patient care and safety is very helpful for patients, families and providers. These data can be used to help patients and providers in the future incorporate processes that can improve patient experience and outcomes after orthopedic trauma injury. The risk-benefit ratio is acceptable.

Conflict of Interest

The study team has no conflict of interest to report.

Sources of funding:

This project has received support from the Foundation for Physical Medicine & Rehabilitation, the National Athletic Trainers' Association and the W. Martin Smith Interdisciplinary Patient Quality and Safety Award.

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