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The Leeds Risk Index: Field-test of a stratified psychological treatment selection algorithm

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Abstract: Clinical guidelines for the treatment of depression and anxiety recommend psychological interventions organised in a stepped care model, where patients initially access low intensity guided self-help followed by high intensity psychotherapies if their symptoms persist. The Leeds Risk Index (LRI) is a data-driven tool that enables clinicians to profile patients into subgroups with *low*, *moderate* or *high risk* of poor response to treatment. A prior retrospective analysis of routine care data suggested that clinical outcomes for *high risk* cases could be improved by directly assigning them to high intensity treatments (stratified care) rather than usual stepped care. This study was the first prospective field-test of a stratified treatment selection approach based on the LRI tool. Post-treatment depression (PHQ-9) and anxiety (GAD-7) remission rates, dropout rates and treatment duration were compared between 157 stratified care cases vs. 125 stepped care controls. The results indicate that stratified care significantly improved the efficiency of psychological treatment, attaining comparable clinical outcomes in a shorter overall treatment duration.

Key terms: depression, anxiety, CBT, stratified care, precision medicine

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Clinical guidelines for the treatment of depression and anxiety problems recommend evidence-based psychological interventions organised in a stepped care model, where patients initially access low intensity self-help interventions guided by qualified practitioners and later have the option to access high intensity psychological therapies if their symptoms persist [1]. Stepped care services are widely available in England and have been shown to be effective, although it is also recognised that around half of patients who access treatment do not attain remission of symptoms [2]. Even if they present with similar symptoms (e.g., depression), patients accessing stepped care services are heterogeneous in other important features such as age, employment, disability, functional impairment, symptom severity and expectations about the benefits of therapy. A recent study found that the above patient-features were significantly associated with post-treatment remission of symptoms [3]. Using the regression weights for each of these features, the authors developed the Leeds Risk Index (LRI), a simple tool that enables clinicians to profile patients into subgroups with *low*, *moderate* or *high risk* of poor response to psychological treatment (Figure 1 – panel A). Applying the LRI profiling tool in a retrospective analysis of data from 1347 patients, the authors found that *high risk* cases tended to have significantly higher remission rates after high intensity therapies by comparison to low intensity guided self-help. On this basis, they proposed that a stratified care approach matching *high risk* cases directly to high intensity therapies could be more cost-effective than stepped care.

The present study was a prospective field-test of the LRI stratified care approach. A team of 12 qualified psychological therapists working in an English stepped care service co-designed a decision algorithm (Figure 1 – panel B) that would enable them to use the LRI tool for psychological treatment selection in a way that is compatible with clinical guidelines [1] which require that cases with certain conditions (e.g., post-traumatic stress disorder) should be directly assigned to high intensity therapies. They applied this decision algorithm to make treatment recommendations for all patients who they consecutively assessed during a 3-month period (N=157). All patients completed the PHQ-9 depression [4] and GAD-7 anxiety [5] measures on a session-to-session basis, following routine outcome monitoring guidelines [2]. The study sample was matched to a sample of 125 control cases from archival clinical records, who had similar baseline

characteristics (LRI profiles) and who accessed routine stepped care. Case-control matching was achieved using a propensity score matching method [6]. We then compared post-treatment reliable and clinically significant improvement (RCSI) rates [3], dropout rates and treatment duration between LRI study cases and matched controls. Statistical analyses included chi-square tests for binary variables, non-parametric comparison of means, and logistic regression to examine LRI profile x treatment interactions. The primary outcome measure was the PHQ-9.

The LRI study sample included mostly females (72.0%), from a white British background (90.2%), with an average age of 34.9 (SD=14.66), of whom 42.1% were unemployed. Mean baseline severity measures were: PHQ-9=15.12 (SD=5.21); GAD-7=13.52 (SD=4.44). Approximately 50.0% had an affective disorder, 34.7% had generalized anxiety disorder, 4.8% had panic disorder, and other conditions were less prevalent. According to the LRI, 28.5% were classified as *low risk*, 56.1% as *moderate risk*, and 15.4% as *high risk* cases. There were no significant differences between study cases and controls in any of the baseline severity measures or LRI classification.

There were significant differences in the treatment pathway of LRI cases versus controls (x^2[DF 2]=11.95, p<.01). Both groups had a similar proportion of cases that only accessed low intensity treatment (cases=67.2%; controls=64.8%). However, a higher number of LRI study cases were fast-tracked to high intensity treatments (24.8% vs. 13.6%), and a lower number of LRI study cases had combined low + high intensity treatments (8% vs. 21.6%). This meant that including the LRI in treatment selection decisions approximately led to an 11% increase in direct allocation to high-intensity treatments.

There were no significant differences in symptom remission (RCSI) rates between cases (45.0%) vs. controls (45.4%) in the full sample (x^2[DF 1]=0.003, p=.96). *High risk* cases had considerably higher depression remission rates in the LRI study sample vs. controls (38.9% vs. 18.8%); however, the interaction term in logistic regression was not statistically significant (Odds Ratio=3.27, p=.17). These findings were consistent in the PHQ-9 and GAD-7 measures. There were significant differences in treatment duration, measured in mean number of weeks between initial assessment and discharge dates (21.03 vs. 28.26). Treatment duration for LRI study cases was approximately 7 weeks shorter than controls (U[250]=6144.50,

p<.01). These differences were unrelated to dropout, since there were no significant differences in dropout rates (~34.2%) between study cases and controls [x^2 (DF 1)=0.29, *p*<.59].

Overall, LRI study cases had similar clinical outcomes attained within a shorter treatment episode and this was unrelated to dropout. These findings indicate that stratified treatment selection reduces the number of cases that have an unnecessary "double dose" of treatment (low + high intensity). *High risk* cases tended to have higher remission rates in the LRI study sample, although this interaction effect was not statistically significant. One explanation might be that this apparent interaction effect is simply due to chance, although it shows the same symptom response pattern observed in a previous study [3]. An alternative explanation is that the present sample was too small to detect the observed moderate effect size (OR=3.27), since this effect is only relevant to a subsample of *high risk* cases (15% of the total sample).

To our knowledge, this is the first prospective field-test of a data-driven and stratified approach to psychological treatment selection, representing an important landmark for the emerging field of precision mental healthcare. However, some important limitations should be considered. The study dataset did not include therapist identifiers, so it was not possible to control for potential therapist effects. Furthermore, we applied propensity score matching to derive comparable groups in a quasi-experimental design, but this does not rule out the possibility that unmeasured confounders could be unbalanced across groups. Large randomised controlled trials are necessary to verify the apparent clinical advantages of matching *high risk* cases to high intensity treatments, although the current evidence convincingly shows that stratified care improves the efficiency of treatment.

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Figure 1. A patient profiling and stratified treatment selection model